

Custom Device Exemption

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

**This guidance document is being distributed for comment purposes only.
Document issued on: January 14, 2014**

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact either Erin Keith or Eric Horowitz at the Center for Devices and Radiological Health (CDRH):

Erin Keith
Office of Device Evaluation (ODE)
301-796-6384
erin.keith@fda.hhs.gov

Eric Horowitz
Office of Compliance (OC)
301-796-5597
eric.horowitz@fda.hhs.gov



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Office of Compliance**

38

Preface

39

40

Additional Copies

42

43 Additional copies are available from the Internet. You may also send an e-mail request to
44 dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-
45 827-8149 to receive a hard copy. Please use the document number 1820 to identify the
46 guidance you are requesting.

47

48

Table of Contents

49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65
66
67
68
69
70
71
72
73
74
75
76
77
78
79
80
81
82
83
84
85
86
87
88
89
90
91
92
93
94
95
96
97
98

I.	Introduction.....	1
II.	Background.....	1
III.	Definitions	2
IV.	No More Than Five Units Per Year of a Device Type.....	3
V.	Questions and Answers/Examples of Custom Devices.....	4
A.	What premarket and postmarket requirements are my custom device exempt from fulfilling?	4
B.	The custom device exemption describes two types of custom devices: one that is specific to the special needs of the physician’s practice, and one that is specific to the patient’s unique physiological/pathology needs. Can a single custom device be both unique to a physician’s practice and the patient’s unique needs?..	5
C.	Can a device subject to an IDE be a custom device?.....	5
	No, a device that is currently being studied or capable of study under an IDE does not meet the definition of a custom device. Additionally, the IDE is a broad exemption under which devices used in clinical investigations that meet IDE requirements are exempt (not only) from sections 514 and 515, but also from section 502, 510, 516, 519, 510(e), 520(f) and section 721 of the FD&C Act. As discussed above, the custom device exemption is more limited; thus, there would be no reason to seek a custom device exemption for a device capable of study under an IDE. Custom devices represent a much narrower category of devices, limited to devices devised for the purpose of treating sufficiently rare conditions or rare physician needs, where conducting clinical investigations would be impractical.	5
D.	What is the relationship between compassionate use and a custom device?.....	5
E.	Can modifications to an existing 510(k)-cleared device be made under the custom device exemption?..	6
F.	How are revisions and servicing of existing valid custom devices included in the total of five units of a device type per year?	6
G.	Are pediatric devices automatically custom devices, simply because the device is for a pediatric population?	6
H.	How should I label my custom device?.....	7
I.	Can I market my custom device to the general public?.....	7
J.	What are some examples of devices that are potential custom devices?.....	7
K.	What are some examples of a device that is not a custom device?.....	8
VI.	Annual Report.....	8
A.	Annual Report – General Contents.....	9
1.	Cover Letter	9
2.	Certification Statement	9
3.	Other Logistical Information	9
B.	Annual Report -- Patient-Centric Custom Device Information	10
	As described in Section IV of this guidance, a custom device is either patient-centric or physician/dentist-centric, but not both. In addition to the requested elements listed in Section V.A. (above) the following elements should be provided to FDA in a Custom Device Annual Report for patient-centric devices to ensure that the conditions listed in sections 520(b)(1) and 520(b)(2) are met.	10
1.	Explanation of how the device satisfies the elements of Section 520(b) of the FD&C Act	10
2.	Summary of Custom Devices Shipped, Used, and Returned	11
3.	Details on Custom Device Use	11
C.	Annual Report –Physician or Dentist-Centric Custom Device Information.....	12
	As described in Section IV of this guidance, a custom device is either considered to be patient-centric or physician/dentist-centric, but not both. In addition to the requested elements listed in Section V.A. (above) the following elements should be provided to FDA in a Custom Device Annual Report for a physician-centric device to ensure that the conditions listed in sections 520(b)(1) and 520(b)(2) are met.	12
1.	Explanation of how the device satisfies the elements of Section 520(b) of the FD&C Act	12
2.	Accommodating a Doctor’s or Dentist’s Special Need	13

Contains Nonbinding Recommendations

Draft - Not for Implementation

99 **3. Details on Custom Device Use**.....13

100 b) Custom device or custom device components. You should provide information on the number of

101 custom devices or custom device components that were shipped, sold, and returned during the reporting

102 period. This includes the product name, brand name, product model number, product catalog number,

103 other product identifier information, product code, and product classification regulation.14

104 D. FDA’s Review of Your Annual Report.....14

105 **VII. Complete Text of Section 520(b) of the Food, Drug and Cosmetic Act**.....14

106 Please see Appendix III for a flow diagram of the decision tree needed to implement the custom device

107 provisions in the FD&C Act.15

108 Appendix I.....16

109 **Appendix II**18

110 **Custom Device Annual Report Truthful And Accurate Statement**18

111 Appendix III19

112 Custom Device Decision Tree.....19

113

Custom Device Exemption

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

The Food and Drug Administration (FDA) has developed this draft document to provide guidance to industry and FDA staff about implementation of the custom device exemption contained in Section 520(b) the Food, Drug and Cosmetic Act (FD&C Act). The guidance provides draft definitions of terms used in the custom device exemption, explains how FDA proposes to interpret the “5 units per year of a particular device type” language contained in section 520(b)(2)(B), describes what information FDA proposes should be submitted in a Custom Device Annual Report (annual report), and provides recommendations on how to submit an annual report for devices distributed under the custom device exemption. FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Effective on July 9, 2012, section 617 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144) required the implementation of changes to the custom device exemption contained in section 520(b) of the FD&C Act. The new provision amended an existing custom device exemption and introduced new concepts and procedures for custom devices, such as:

- devices created or modified in order to comply with the order of an individual physician or dentist;
- the potential for multiple units of a device type (not to exceed 5 units per year) qualifying for the custom device exemption; and

Contains Nonbinding Recommendations
Draft - Not for Implementation

- 153 • annual reporting requirements by the manufacturer to FDA about devices
154 manufactured and distributed under section 520(b) of the FD&C Act.
155

156 Although the revisions to the custom device exemption clarify the availability of the
157 exemption in certain circumstances – for example, when more than one (but fewer than five)
158 devices are manufactured per year and when modifications are made to a marketed device –
159 the new statutory language does not create a broad, new exemption from sections 514 and
160 515 of the FD&C Act. Under the revised provision, as under the original custom device
161 exemption, custom devices should represent a narrow category for which, because of the
162 rarity of the patient’s medical condition or physician’s special need, requiring compliance
163 with premarket review requirements and performance standards under sections 514 and 515
164 of the FD&C Act is impractical.
165

166 Historically, practitioners and manufacturers have sought custom device exemptions for
167 devices more properly considered under a compassionate use protocol. FDA notes that
168 some devices deemed ineligible for custom devices status prior to FDASIA would remain
169 ineligible under the new provision, but may qualify for compassionate use. Although a full
170 discussion of compassionate use is outside the scope of this guidance, a short discussion of
171 compassionate use is included in the Question and Answer section of this draft guidance.

172 **III. Definitions**

173 **Device Type**

174 A generic device type is defined as a grouping of devices that do not differ significantly
175 in purpose, design, materials, energy source, function, or any other feature related to
176 safety and effectiveness, and for which similar regulatory controls are sufficient to
177 provide reasonable assurance of safety and effectiveness. (21 CFR 860.3(i)). For the
178 purposes of this guidance, “device type” more specifically describes devices with
179 common design characteristics and indication/intended use, such as those devices defined
180 by an FDA classification regulation or product code.
181

182 **Importer**

183 “Importer” means any person who imports a device into the United States.¹
184

185 **Necessarily Deviates**

186 “Necessarily deviates” means that a device should be sufficiently unique so that clinical
187 investigations would be impractical, and could not be performed to demonstrate conformance
188 to applicable performance standards and/or support premarket review.²
189

190 **Not Generally Available**

191 A device that is “not generally available” is a device not generally available in finished form
192 and that is not advertised by the manufacturer, importer, or distributor for manufacture and/or
193 commercial distribution in the United States and is of a type available [for introduction into

¹ 21 CFR 806.2(f).

² 48 FR 248 Pages 56778, 56796, December 23, 1983.

Contains Nonbinding Recommendations
Draft - Not for Implementation

194 commercial distribution] in quantities of less than five units per year. This includes, but is
195 not limited to, devices without electronic or hard copy literature, promotional material, or
196 testimonials available. For example, a manufacturer could make a custom device in response
197 to an unsolicited request by a physician who specifies unique design inputs when no similar
198 product is commercially available in the United States and clinical investigations would be
199 impractical.

200

201 **Order of a Physician**

202 “Order of a physician” refers to the written request for a custom device made by a physician,
203 dentist, or other specially qualified person designated by FDA regulation. In the case of a
204 prescription device, this would include the written or electronic prescription.

205

206 **Special Need**

207 A “special need” is a need that is related to unusual anatomical features of the individual
208 doctor, dentist or any other specially qualified person designated under regulations
209 promulgated by the Secretary.³

210

211 **Sufficiently Rare Condition**

212 A “sufficiently rare condition” is a condition in a patient population in which the incidence or
213 prevalence is so small that conducting clinical investigations on such device would be
214 impractical.

215

216 **Unique Pathology**

217 “Unique pathology” is pathological anatomy that no other device is domestically available to
218 treat.

219

220 **Unique Physiologic Condition**

221 A “unique physiologic condition” is one that no other device is domestically available to
222 treat.

223 **IV. No More Than Five Units Per Year of a Device Type**

224 Under FDASIA, “devices” that qualify for the custom device exemption contained in section
225 520(b) of the FD&C Act are “limited to no more than 5 units per year of a particular device
226 type” that otherwise meet all the requirements necessary to qualify for the custom device
227 exemption.

228

229 FDA interprets the five units in terms of five new custom device cases per year (i.e., five new
230 patients for the patient-focused custom device or five new physicians for the physician-
231 focused custom device, assuming all other required elements for the custom device
232 exemption are satisfied). The five unit limitation includes all devices provided by a
233 manufacturer to, and remaining in the possession of, the ordering physician and/or the
234 patient. FDA does not intend to include in the tally of five units per year any extra units that
235 are produced for a unique case because of sizing concerns, so long as those devices not used

³ 43 FR 20726, 20747-49, May 12, 1978; 45 FR 3732 and 3740, January 18, 1980.

Contains Nonbinding Recommendations

Draft - Not for Implementation

236 for that unique case are returned to the manufacturer, and not redistributed without either
237 valid marketing authorization or for a subsequent valid custom device case. FDA
238 recommends that these extra units be destroyed and a signed record of the destruction be
239 maintained in the manufacturer’s device history record. For example, if four sizes of a valid
240 custom orthopedic implant are manufactured for a specific patient’s need and one device is
241 ultimately implanted into the patient, then the remaining three sizes should be returned to the
242 manufacturer. If these units are not returned to the manufacturer, then FDA considers four of
243 the five total units per year to have been used for this one patient. On the other hand, if the
244 three other units are returned to the manufacturer, only one of the five units per year will
245 have been used to treat this patient, provided the returned devices are not redistributed
246 without either valid marketing authorization or for use in a subsequent valid custom device
247 case.

248

249 The devices used in the case where a patient requires multiple devices of the same type (such
250 as bilateral conditions) requiring treatment of multiple anatomical locations within a given
251 reporting year, will be considered one unit for the purposes of tallying the five units of a
252 device type per year, so long as those devices not used for that unique case are returned to the
253 manufacturer, and not redistributed without either valid marketing authorization or for use in
254 a subsequent valid custom device case. For example, in the event valid bilateral custom joint
255 replacement devices (such as might occur in bilateral knee replacement procedures) are
256 required for a given patient, so long as the patient’s joint replacement procedures occur in the
257 same reporting year, and all unused product is returned to the manufacturer, FDA will
258 consider the multiple joint replacement devices needed to treat the bilateral patient as a single
259 unit in the tally of five units per year of a device type. If the treatment of the patient’s
260 multiple anatomical locations occur during different reporting years, each treatment will
261 contribute one unit each to the tally for the reporting year in which the treatment occurs (so
262 long as devices not used for that unique case are returned to the manufacturer, and not
263 redistributed without either a valid marketing authorization or for use in a subsequent valid
264 custom device case).

265 **V. Questions and Answers/Examples of Custom Devices**

266 **A. *What premarket and postmarket requirements are my custom device exempt***
267 ***from fulfilling?***

268 Under Section 520(b) of the FD&C Act, custom devices are exempt from Premarket
269 Approval (PMA) requirements, as well as conformance to mandatory performance
270 standards.⁴ Custom Devices are *not* exempt from any other requirements, including,
271 but not limited to, the Quality System Regulation, including Design Controls (21 CFR
272 Part 820); Medical Device Reporting (21 CFR Part 803); Corrections and Removals
273 (21 CFR Part 806); and Registration and Listing (21 CFR Part 807).

⁴ A device not covered by an existing marketing approval would require either a PMA or a valid exemption to the requirements to obtain PMA approval in order to introduce the device into interstate commerce. Examples of potential valid exemptions or alternatives to the PMA requirement include: (1) establishing the substantial equivalence of the new device to a valid predicate device, (2) approval of an Investigational Device Exemption (IDE) or (3) meeting all the requirements for the custom device exemption.

Contains Nonbinding Recommendations

Draft - Not for Implementation

274 **B. *The custom device exemption describes two types of custom devices: one***
275 ***that is specific to the special needs of the physician’s practice, and one that***
276 ***is specific to the patient’s unique physiological/pathology needs. Can a***
277 ***single custom device be both unique to a physician’s practice and the***
278 ***patient’s unique needs?***

279 No, the custom device provision allows for two different categories of custom devices
280 to be developed. One is patient-centric and the other is physician/dentist-centric; a
281 custom device cannot be both patient and physician/dentist-centric. A custom device
282 made to treat a patient’s sufficiently rare condition leaves the medical/dental practice
283 with the patient, while a custom device made to satisfy a sufficiently unique special
284 need for the physician/dentist stays with that physician/dentist for use in his/her
285 practice.

286 **C. *Can a device subject to an IDE be a custom device?***

287 No, a device that is currently being studied or capable of study under an IDE does not
288 meet the definition of a custom device. Additionally, the IDE is a broad exemption
289 under which devices used in clinical investigations that meet IDE requirements are
290 exempt (not only) from sections 514 and 515, but also from section 502, 510, 516,
291 519, 510(e), 520(f) and section 721 of the FD&C Act. As discussed above, the
292 custom device exemption is more limited; thus, there would be no reason to seek a
293 custom device exemption for a device capable of study under an IDE. Custom
294 devices represent a much narrower category of devices, limited to devices devised for
295 the purpose of treating sufficiently rare conditions or rare physician needs, where
296 conducting clinical investigations would be impractical.

297 **D. *What is the relationship between compassionate use and a custom device?***

298 Devices that do not meet all of the elements of the custom device definition described
299 in section 520(b) of the Act may still qualify for compassionate use. FDA provides
300 information on how to request a compassionate use of an unapproved device in the
301 guidance document “[Guidance on IDE Policies and Procedures](#)”
302 ([http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocu](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080202.htm)
303 [ments/ucm080202.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080202.htm)).
304

305 “Compassionate use” of an unapproved device may occur when a device that is being
306 tested in a clinical trial under IDE is the only option available for a patient faced with
307 a serious condition. In cases where a sponsor seeks compassionate use of a device
308 that does not have an approved IDE in effect, please contact the CDRH IDE Staff to
309 discuss potential compassionate use of the device. All compassionate uses require
310 prior FDA approval under 21 CFR 812.35(a) and this approval must be obtained
311 before the device is used. In order to obtain Agency approval, the sponsor should
312 submit an IDE supplement requesting approval for a protocol deviation in order to
313 treat the patient. Please refer to the guidance listed above for more information on the
314 compassionate use of unapproved devices.
315

Contains Nonbinding Recommendations

Draft - Not for Implementation

316
317

E. Can modifications to an existing 510(k)-cleared device be made under the custom device exemption?

318
319
320
321
322
323
324
325
326
327
328

Modifications to a 510(k)-cleared device that maintains the original intended use and could be clinically studied would not be considered appropriate as a custom device and should be handled in accordance with 21 CFR 807.81 and the guidance document “[Deciding When to Submit a 510\(k\) for a Change to an Existing Device \(K97-1\)](http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocument/ucm080235.htm)” (<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocument/ucm080235.htm>) (i.e., submission of a new 510(k) application or documentation to the design history file explaining why the change does not require a new 510(k), as appropriate). However, if an existing 510(k)-cleared device is modified in order to treat a unique pathology or unique physiological condition, which render it incapable of clinical study, the device could potentially qualify as a custom device.

329
330
331
332
333
334
335
336
337
338
339
340
341
342
343

It is worth noting that FDA reviews, clears, and approves for marketing many patient-specific devices (also referred to as patient-matched devices). Patient-specific devices are, in general, ones in which ranges of different specifications have been approved or cleared to treat patient populations that can be studied clinically. Premarket submissions for such devices are sometimes referred to as “envelope” submissions because approval or clearance of the submission covers the entire range of specifications supported by data in the submission. The final manufacturing of these devices can be delayed until the physician provides imaging data or other information to the manufacturer to finalize the specifications of the device within the cleared or approved ranges. As a result, the device is specifically tailored for the patient. While these devices have sometimes colloquially been referred to as “customized,” these devices *are not custom devices* per the requirements of the custom device exemption in the FD&C Act. Marketing applications are required for these device types because both the device and patient population can be defined and studied.

344
345

F. How are revisions and servicing of existing valid custom devices included in the total of five units of a device type per year?

346
347
348
349
350
351
352
353

A device that meets all of the requirements of section 520(b) of the FD&C Act when initially distributed will not be counted against the five units of a device per year if it has later been revised or serviced, *provided that* such revision or servicing is performed in furtherance of meeting the special needs of the person, physician, or dentist for whom the custom device was initially intended prior to such revision and/or servicing. You should contact CDRH’s Office of Compliance to discuss the specifics of your situation prior to undertaking the revision or servicing of such device, as discussed herein.

354
355

G. Are pediatric devices automatically custom devices, simply because the device is for a pediatric population?

356
357

No. Pediatric patient populations may be studied just as with adult populations, and to the extent that it is possible, they should be studied so that proper labeling of a

Contains Nonbinding Recommendations
Draft - Not for Implementation

358 device may be created. The proper labeling can guide users toward a better
359 understanding of performance characteristics of the device.

360 ***H. How should I label my custom device?***

361 Custom devices remain subject to all of the labeling requirements, such as the
362 requirement that the labeling bear adequate directions for use, may not be false or
363 misleading, and many other requirements related to labeling, including 21 CFR 801.1.
364 In addition, the labeling of a custom device should include the following information:
365 (1) a statement the device is a custom device; (2) the name of the ordering
366 physician/dentist and patient (if applicable) that the device is intended to treat; (3)
367 indications for use; (4) sterilization status; (5) relevant composition information
368 (materials, components, etc.); and (6) storage conditions.⁵

369 ***I. Can I market my custom device to the general public?***

370 No. A custom device is made as a special order at the request of a physician/dentist
371 to be used on patients with a sufficiently rare condition or for a physician/dentist's
372 special needs (i.e., unusual anatomical features) for no more than five units per year
373 of a device type. Section 520(b)(1)(C) sets forth that a custom device is not, among
374 other things, made generally available in finished form through labeling or
375 advertising.

376 ***J. What are some examples of devices that are potential custom devices?⁶***

377 A possible example of a custom device might be one manufactured for a patient with
378 skeletal dysplasia requiring a total hip replacement procedure to treat her
379 osteoarthritis. The patient's skeletal dysplasia could be characterized by
380 abnormalities in the growth and/or remodeling of cartilage and bone, resulting in
381 short stature and angular and torsional deformities of the patient's hip. In this
382 particular case it is possible that the patient's unique pathological anatomy might not
383 be successfully treated with the currently available total hip replacement devices
384 marketed in the United States. Other elements of the custom device exemption would
385 need to be met, such as the patient population being too small to support a clinical
386 study.

387
388 Another possible example of a custom device might be an artificial cervical disc
389 replacement for reconstruction of the cervical disc following cervical discectomy for
390 treatment of cervical radiculopathy in a 7'2" male patient. Under this hypothetical
391 scenario, the osseous dimensions of this patient's cervical spine are such that the
392 dimensions exceed those which would be accommodated by a cervical disc available

⁵ For additional information on device labeling, refer to 21 CFR Part 801 and "[Guidance on Medical Device Patient Labeling](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070782.htm)" (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070782.htm>).

⁶ This is not intended to be an exhaustive list of devices that might satisfy the custom device exemption, and it represents only a subset of the information needed to meet the statutory requirements for a valid custom device. If you have questions as to whether your scenario might satisfy the custom device exemption, we encourage you to contact CDRH's Office of Compliance to discuss.

Contains Nonbinding Recommendations

Draft - Not for Implementation

393 in the United States and the patient represents a population which, at this time,
394 appears to be too small to support a clinical study.

395
396 An additional example of a possible custom device might be one manufactured for a
397 toddler needing occipital condyle screws after surviving a severe car accident, leaving
398 her paralyzed from the neck down and in need of instrumentation that would help
399 hold her head up. Her physician concludes that an occiput to C2 posterior cervical
400 fusion would be best for the patient. In the United States, there are no cleared or
401 approved screws for placement in the occipital condyle available in the sizes needed
402 for this pediatric patient population. At this time the pediatric patient population
403 needing posterior occipital condyle fusion within the size range needed for the toddler
404 could be too small to support a clinical study. This scenario might satisfy the custom
405 device exemption, and the physician should request custom occipitocervical implants
406 for non-standard, pediatric sized screws for use in the occiput, cervical spine, and
407 upper thoracic spine of this specific patient.

408 ***K. What are some examples of a device that is not a custom device?***

409 A primary total knee replacement (TKR) patient received company X's TKR device.
410 Later, the patient needs a revision of one side of the TKR joint replacement, and
411 could have this accomplished by utilizing company X's off-the-shelf component for
412 revision surgeries. However, the hospital where the patient's doctor practices only
413 uses company Y's products. The doctor would like to request a custom company Y
414 component be made to replace the patient's failing company X component. This
415 situation would not satisfy the requirements for a custom device exemption because a
416 device is available domestically that could be used to treat the patient. See Section
417 520(b)(1)(D) of the FD&C Act.

418 **VI. Annual Report**

419 The statutory amendments to the custom device exemption under FDASIA added a new
420 reporting requirement:

421
422 *"... the manufacturer of such [custom]device notifies the Secretary on an annual basis, in a*
423 *manner to be prescribed by the Secretary, of the manufacture of such device."*

424
425 The manufacturer of the custom device must report to FDA annually, as required by section
426 520(b)(2)(C) of the FD&C Act, on the custom devices it supplied. The annual report should
427 include the number of patients who received a new device or revisions of a previous custom
428 device. Additionally, multiple custom devices or components used in one patient should be
429 accounted for in the annual report. As noted in Section III of this guidance, typically only
430 new custom devices will be counted toward the maximum amount of five units per year of a
431 particular device type. However, revisions to an existing custom device should be accounted
432 for in the annual report. In addition, the number of custom devices both provided to, and
433 returned by, physicians or dentists to accommodate unusual anatomical features of the
434 individual patient, physician or dentist should be accounted for in the annual report.

435

Contains Nonbinding Recommendations

Draft - Not for Implementation

436 The annual report should summarize the number of custom devices manufactured and
437 distributed in the United States during a 1-year reporting period. Each annual report should
438 cover a given calendar year. The first report should contain retrospective information on
439 custom devices provided by manufacturers from the date of enactment of FDASIA (on July
440 9, 2012) to the date of the first report. For all subsequent reporting periods, the report should
441 be submitted to FDA within the first quarter of the following calendar year (e.g., by no later
442 than March 31.). FDA will not enforce the new annual reporting requirement until the end of
443 the calendar year following publication of the final guidance; however, FDA encourages
444 manufacturers to submit the information required by the statute in any format in advance of
445 the finalized guidance being published.

446
447 A complete annual report should include all of the information as set forth below. FDA
448 believes it can review a complete annual report more efficiently and may be less likely to
449 request additional information. The following sections provide guidance on how to submit
450 the annual notification (e.g., the annual report) to FDA and the content of that report for both
451 patient-centric and physician-centric custom devices.

452 ***A. Annual Report – General Contents***

453 The following general information should be included in both patient-centric and
454 physician-centric annual reports.

455 **1. Cover Letter**

456 Your report should include a cover letter that clearly states that the reason for
457 the submission is a “Custom Device Annual Report” in the reference line.
458 The cover letter should contain your complete contact information (i.e., the
459 company name, address, URL, contact person, title, phone number, fax
460 number, and email address). In addition to describing the reason for the
461 submission in the reference line, the cover letter should also clearly identify
462 the name of the custom devices and include the signature of the contact person
463 or other responsible party within the company. The cover letter should also
464 specify the reporting period (i.e., the dates the reporting period begins and
465 ends).

466 **2. Certification Statement**

467 Your report should include a signed Custom Device Annual Report Truthful
468 and Accurate certification statement that indicates that the submitter is an
469 authorized representative for the manufacturer and that all the information
470 provided in the paper and electronic copies of the Custom Device Annual
471 Report is truthful and accurate to the best of your knowledge and that no
472 material fact has been omitted. See Appendix II for a copy of the statement
473 certificate.

474 **3. Other Logistical Information**

475 Your Custom Device Annual Report should be written in the English
476 language. Any material provided in a foreign language should be
477 accompanied by an accurate and complete English translation. You should
478 send two copies of your Custom Device Annual Report to the address below.

Contains Nonbinding Recommendations
Draft - Not for Implementation

479 We strongly encourage that one or both of your copies be an electronic copy,
480 which can be e-mailed to customdevices@fda.hhs.gov.

481
482 Attn: Custom Device Annual Report Submission Coordinator
483 Division of Analysis and Program Operations
484 Office of Compliance
485 Center for Devices and Radiological Health
486 U.S. Food and Drug Administration
487 WO66, Room 2654
488 10903 New Hampshire Avenue
489 Silver Spring, MD 20993-0002

490 ***B. Annual Report -- Patient-Centric Custom Device Information***

491 As described in Section IV of this guidance, a custom device is either patient-centric
492 or physician/dentist-centric, but not both. In addition to the requested elements listed
493 in Section V.A. (above) the following elements should be provided to FDA in a
494 Custom Device Annual Report for patient-centric devices to ensure that the
495 conditions listed in sections 520(b)(1) and 520(b)(2) are met.

496 **1. Explanation of how the device satisfies the elements of Section 520(b)**
497 **of the FD&C Act**

498 In your report, you should include a justification for how or why the device
499 manufactured to treat an individual patient meets each of the following
500 conditions contained in the FD&C Act⁷:

501 a) In order to explain how sections 520(b)(1)(B) and (b)(2)(A) are met,
502 you should provide an explanation of why the device necessarily deviates
503 from the premarket requirements including treating a sufficiently rare
504 condition such that conducting clinical investigations are impractical. You
505 may include information on the incidence or prevalence of the condition
506 or disease the device is intended to diagnosis, treat, mitigate, prevent, or
507 cure or is otherwise intended to affect the structure or any function of the
508 body of man. References for the data provided should also be included. If
509 the incidence or prevalence material referenced is not available in the
510 published literature, you should include a copy of the reference in the
511 annual report. If you believe that information on the incidence or
512 prevalence of the condition or disease is not available, please provide an
513 explanation why you believe the information is not available.

514 b) In order to explain how section 520(b)(1)(A) is met, you should
515 indicate whether the device is a newly created device or modified from an
516 existing legally marketed device in order to comply with the order of an
517 individual physician or dentist.

518 c) In order to explain how section 520(b)(1)(C) is met, you should attest
519 that the device is not generally available in the United States in finished

⁷ See Section VI of this guidance document for the complete text contained in section 520(b) of the FD&C Act.

Contains Nonbinding Recommendations

Draft - Not for Implementation

520 form through labeling or advertising by the manufacturer, importer, or
521 distributor for commercial distribution.

522 d) In order to explain how part of section 520(b)(1)(D) and section
523 520(b)(2)(B) are met, you should provide a complete description of the
524 device including device type (e.g., product code and classification
525 regulation, as applicable), as well as the patient's unique pathology or
526 physiological condition the device was designed to treat.

527 e) In order to show that section 520(b)(1)(D) is met, you should provide a
528 statement that no other device is domestically available to treat the
529 patient's unique pathology or physiological condition. You should
530 maintain records of the evaluation that you used to determine that no other
531 device is domestically available to treat the patient's unique pathology or
532 physiological condition.

533 f) In order to explain how section 520(b)(1)(E)(ii) is met, you should
534 provide the name of the individual patient in the physician's or dentist's
535 order.

536 g) In order to explain how section 520(b)(1)(F) is met, you should state
537 whether the device is assembled from components or manufactured and
538 finished on a case-by-case basis to accommodate the unique needs of
539 individuals. Additionally, you should explain under section 520(b)(1)(G)
540 whether the device or device components have common, standardized
541 design characteristics, chemical and material compositions, and the same
542 manufacturing processes as commercially distributed devices.

543 2. Summary of Custom Devices Shipped, Used, and Returned

544 You should provide an annual summary of all the custom devices supplied,
545 used, and returned during the reporting period. This includes a name or
546 description of the device, the classification regulation (if applicable), and
547 product code (if available). This summary should also include information on
548 the number of each type of device that was shipped, used/remaining with the
549 patient (e.g., implanted) in new and revision patients, and the number of
550 custom devices that were returned to the manufacturer/distributor. In order to
551 facilitate FDA's review of your summary report, we recommend using the
552 format described in Table 1 of Appendix I for reporting this information.

553 3. Details on Custom Device Use

554 You should provide the following detailed information on custom devices
555 manufactured during the reporting period.
556

557 a) Patient Information. You should indicate the total number of patients
558 receiving custom devices. This should be broken down into patients
559 receiving a new device, and those undergoing revisions of previously
560 existing custom devices. Additional information on the patients should
561 also be provided. This includes patient identifiers (e.g., initials/name and
562 age), date of the procedure or implant, and a description of the condition

Contains Nonbinding Recommendations
Draft - Not for Implementation

563 that necessitated use of a custom device.

564 b) Physician information. You should provide the name, address, and
565 other contact information for the treating physician for each patient
566 procedure.

567 c) Custom device or custom device components. For each custom device
568 or device component remaining with the patient, you should provide
569 details on each device or device component. These details should include
570 the product name, brand name, product model number, product catalog
571 number, other product identifier information, product code, and product
572 classification regulation.

573 In order to facilitate FDA’s review of your detailed custom device report,
574 FDA recommends the format described in Table 2 in Appendix I for
575 presenting patient, physician, and device information.

576 ***C. Annual Report –Physician or Dentist-Centric Custom Device Information***

577 As described in Section IV of this guidance, a custom device is either considered to
578 be patient-centric or physician/dentist-centric, but not both. In addition to the
579 requested elements listed in Section V.A. (above) the following elements should be
580 provided to FDA in a Custom Device Annual Report for a physician-centric device to
581 ensure that the conditions listed in sections 520(b)(1) and 520(b)(2) are met.

582 **1. Explanation of how the device satisfies the elements of Section 520(b)**
583 **of the FD&C Act**

584 In your report, you should include a justification for how or why the device
585 manufactured meets the special needs of a doctor or dentist in the course of
586 his/her professional practice and satisfies each of the following conditions
587 contained in the FD&C Act⁸:

588 a) In order to explain how sections 520(b)(1)(B) and (b)(2)(A) are met,
589 you should provide an explanation of why the device necessarily deviates
590 from the premarket requirements including addressing a sufficiently rare
591 condition such that conducting clinical investigations are impractical. You
592 may include information on the incidence or prevalence of the condition
593 or disease the device is intended to diagnose, treat, mitigate, or prevent.
594 References for the data provided should be included. If the incidence or
595 prevalence material referenced is not available in the published literature,
596 you should include a copy of the reference in the annual report. In
597 addition, you should include an explanation of why conducting clinical
598 investigations on such device would be impractical. If you believe that
599 information on the incidence or prevalence of the condition or disease is
600 not available, please identify why you believe the information is not
601 available.

⁸ See Section VI of this guidance document for the complete text contained in section 520(b) of the FD&C Act.

Contains Nonbinding Recommendations

Draft - Not for Implementation

- 602 b) In order to explain how section 520(b)(1)(A) is met, you should
603 indicate if the device was a newly created device or modified from an
604 existing legally marketed device in order to comply with the order of an
605 individual physician or dentist, as well as the name of the individual
606 doctor or dentist in the order.
- 607 c) In order to explain how section 520(b)(1)(C) is met, you should attest
608 that the device is not generally available in the United States in finished
609 form through labeling or advertising by the manufacturer, importer, or
610 distributor for commercial distribution.
- 611 d) In order to explain how part of section 520(b)(1)(D) and section
612 520(b)(2)(B) are met, you should provide a complete description of the
613 device including device type (i.e., product code and classification
614 regulation as applicable), as well as the doctor's or the dentist's special
615 need that the device was designed to meet.
- 616 e) In order to show that sections 520(b)(1)(D) and 520(b)(1)(E)(i) are
617 met, you should provide a statement that no other device is domestically
618 available to address the doctor's or dentist's special need in the course of
619 conducting his/her practice. You should maintain records of the
620 evaluation that you used to determine that no other device is domestically
621 available to address the doctor's or dentist's special needs are met.
- 622 f) In order to explain how section 520(b)(1)(F) is met, you should
623 provide an explanation if the device was assembled from components or
624 manufactured and finished on a case-by-case basis to accommodate the
625 special needs of individuals described above. Additionally, you should
626 explain under section 520(b)(1)(G) whether the device or device
627 components have common, standardized design characteristics, chemical
628 and material compositions, and manufacturing processes as commercially
629 distributed devices.

2. Accommodating a Doctor's or Dentist's Special Need

631 You should provide an annual summary of all the custom devices both
632 supplied to, and returned by, a physician or dentist to accommodate a special
633 need. This information should include the name or description of the device,
634 classification regulation, and product code (if available). This summary
635 should also include information on the number of each type of device that was
636 shipped/used during the reporting period and the number of custom devices
637 that were returned to the manufacturer/distributor. In order to facilitate FDA's
638 review of your summary custom device report, we recommend the format
639 described in Table 1 in Appendix I for reporting this information.

3. Details on Custom Device Use

641 You should provide the following detailed information on custom devices
642 distributed during the reporting period:

- 643 a) Physician information. You should provide the name, address, and
644 other contact information for the doctor or dentist ordering the custom

Contains Nonbinding Recommendations
Draft - Not for Implementation

645 device.

646 b) Custom device or custom device components. You should provide
647 information on the number of custom devices or custom device
648 components that were shipped, sold, and returned during the reporting
649 period. This includes the product name, brand name, product model
650 number, product catalog number, other product identifier information,
651 product code, and product classification regulation.

652 In order to facilitate FDA’s review of your detailed custom device report,
653 FDA recommends the format described in Table 3 in Appendix I for
654 presenting physician and device information.

655 ***D. FDA’s Review of Your Annual Report***

656 FDA's review of annual reports allow the agency to assess several important issues
657 related to the manufacture and distribution of custom devices. These issues include
658 the adequacy of report documentation and fulfillment of the requirements of section
659 520(b) of the FD&C Act. If we find that the information provided in your annual
660 report is insufficient to allow a complete review, we may request additional
661 information by letter, telephone, or e-mail.⁹ If we only need clarification of an issue,
662 we may communicate on such issues via telephone or e-mail, whichever we believe
663 will be the most efficient.

664 **VII. Complete Text of Section 520(b) of the Food, Drug**
665 **and Cosmetic Act**

666 Section 520(b) (21 U.S.C. 360j(b)) is amended to read as follows:

667 (b) CUSTOM DEVICES.—

668 (1) IN GENERAL.—The requirements of sections 514 and 515 shall not apply to a device
669 that—

670 (A) is created or modified in order to comply with the order of an individual
671 physician or dentist (or any other specially qualified person designated under
672 regulations promulgated by the Secretary after an opportunity for an oral hearing);

673 (B) in order to comply with an order described in subparagraph (A), necessarily
674 deviates from an otherwise applicable performance standard under section 514 or
675 requirement under section 515;

676 (C) is not generally available in the United States in finished form through labeling or
677 advertising by the manufacturer, importer, or distributor for commercial distribution;

678 (D) is designed to treat a unique pathology or physiological condition that no other
679 device is domestically available to treat;

680 (E)(i) is intended to meet the special needs of such physician or dentist (or other
681 specially qualified person so designated) in the course of the professional practice of

⁹ The FD&C Act now requires that custom device manufacturers submit annual reports for all devices distributed under the custom device exemption. Without submission of the required annual report to FDA, any devices distributed as “custom devices” would not be exempted from any applicable premarket requirements.

Contains Nonbinding Recommendations
Draft - Not for Implementation

682 such physician or dentist (or other specially qualified person so designated); or (ii) is
683 intended for use by an individual patient named in such order of such physician or
684 dentist (or other specially qualified person so designated);

685 (F) is assembled from components or manufactured and finished on a case-by-case
686 basis to accommodate the unique needs of individuals described in clause (i) or (ii)
687 of subparagraph (E); and

688 (G) may have common, standardized design characteristics, chemical and material
689 compositions, and manufacturing processes as commercially distributed devices.

690 (2) LIMITATIONS.—Paragraph (1) shall apply to a device only if—

691 (A) such device is for the purpose of treating a sufficiently rare condition, such that
692 conducting clinical investigations on such device would be impractical;

693 (B) production of such device under paragraph (1) is limited to no more than 5 units
694 per year of a particular device type, provided that such replication otherwise complies
695 with this section; and

696 (C) the manufacturer of such device notifies the Secretary on an annual basis, in a
697 manner prescribed by the Secretary, of the manufacture of such device.

698 (3) GUIDANCE.—Not later than 2 years after the date of enactment of this section, the
699 Secretary shall issue final guidance on replication of multiple devices described in paragraph
700 (2)(B).

701 Please see Appendix III for a flow diagram of the decision tree needed to implement the
702 custom device provisions in the FD&C Act.

Appendix I

Format for Summary Data Tables

703

704

705

706 Table 1. Summary of Custom Devices Shipped, Used and Returned

Custom Device Name	Product Code	Number Shipped	Number of New Cases Patient-Centric or Physician-Centric (as applicable)	Number of Revision Cases (Patient-Centric or Physician-Centric)	Number Returned

707

708 Table 2. Patient-Centric Devices - Summary of Patient, Physician and Device Information for Patient-Centric Devices

Patient Identifiers	Date of procedure/implant	Description of the condition that necessitated use of a custom device and alternative treatments	Name and address of physician	Custom device name or custom device components	Other relevant Information
				Product name, Brand name, Product model number, Product catalog number Other product identifier information Product code, Product classification regulation, Material composition	

709

Contains Nonbinding Recommendations
Draft - Not for Implementation

710 Table 3. Physician or Dentist-Centric Devices - Summary of Physician, Dentist and Device Information

Physician name, degree and address	Date(s) of procedures	Description of special need necessitating custom device	Custom device name or custom device components	Other relevant information
			Product name, Brand name, Product model number, Product catalog number, Other product identifier information, Product code, Product classification regulation, Material composition	

711

Appendix II

Custom Device Annual Report Truthful And Accurate Statement

712

713

714

715

716 I certify that, in my capacity as *(the position held in company)* of

717 *(company name)*, I believe to the best of my knowledge, that all data

718 and information submitted in the custom device annual report are truthful and

719 accurate and that no material fact has been omitted.

720

721

722 _____

723 (Signature)

724 _____

725 (Typed Name)

726 _____

727 (Date)

728

729

730

731

732

733

734

735

736
737
738
739

Appendix III Custom Device Decision Tree

Note the term physician in the decision tree stands for physician, dentist or specially qualified person as noted in Section 520(b) of the FD&C Act.

