UNITED STATES FOOD & DRUG ADMINISTRATION

Custom Device Exemption:
Annual Reporting

OMB Control No. 0910-0767

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of section 520 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144). Section 520(b) of the FD&C Act sets forth the requirements that must be met in order for a device to qualify for a custom device exemption. Section 520(b) exempts "*custom devices*" from performance standard or premarket approval requirements under section 514 and 515 of the FD&C Act, if certain criteria are met. While custom devices are exempt from Premarket Approval (PMA) requirements and conformance to mandatory performance standards, they remain subject to all other requirements, including the *Quality System Regulation* in 21 CFR part 820 (information collection approved under OMB control no. 0910-0073); *Medical Device Reporting* in 21 CFR part 803 (information collection approved under OMB control no. 0910-0497); *Labeling* in 21 CFR Part 801 (information collection approved under OMB control no. 0910-0485); *Corrections and Removals* in 21 CFR Part 806 (information collection approved under OMB control no. 0910-0359; and *Registration and Listing* in 21 CFR Part 807 (information collection approved under OMB control no. 0910-0625. Custom devices are limited to use in treating a "*sufficiently rare condition, such that conducting clinical investigations on such device would be impractical*" and production of the device must be limited to no more than 5 units per year of a particular device type.

The guidance document entitled, "*Custom Device Exemption: Guidance for Industry and FDA Staff*" explains how FDA interprets the "5 units per year of a particular device type" language contained in section 520(b)(2)(B) of the FD&C Act, describes what information 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.

We therefore request OMB approval for the information collection associated with custom device exemption annual device reporting as set forth in section 520 of the FD&C Act and explained in referenced guidance document.

2. Purpose and Use of the Information Collection

We use information provided in the custom device exemption annual report to monitor the safety of these devices. Respondents to this collection of information are typically private sector for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

Currently, the reports are prepared as hard copy documents and submitted by mail.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

FDA does not have an estimate on the number of respondents to the information collection are small businesses. FDA aids small business in dealing with the requirements of the regulations by providing guidance and information through the Division of Industry and Consumer Education (DICE), and through the scientific and administrative staff, workshops in which FDA Staff participate, and through the our CDRH website at http://www.fda.gov/MedicalDevices/default.htm. These efforts help to assure that the burden on all manufacturers, including small manufacturers, is minimized.

6. Consequences of Collecting the Information Less Frequently

A manufacturer is only required to submit the report on custom devices on an annual basis by March 31st of the next calendar year. FDA does have the right to ask for additional information if its determined that the information submitted in the annual report is insufficient to allow for a complete review. However, if FDA only needs clarification of an issue then they may communicate on such issue via telephone or e-mail. Therefore, we estimate that the information will only be collected annually.

The information collected in the annual report is necessary for FDA to ensure that devices that meet the qualification of a custom device are exempt from premarket review. The consequence of a manufacturer not submitting an annual report would be that a manufacturer would have to submit a premarket application to allow marketing of the medical device instead of use of the custom device exemption.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the **FEDERAL REGISTER** of 02/21/2020 (85 FR 10175). FDA did not receive any comments.

9. Explanation of Any Payment or Gift to Respondents

No payment of gifts in any manner or form shall be provided to respondents to this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate handling of information collected. Although, unsolicited PII from manufacturers may be provided with submission, we redact this information before it is stored in an FDA system. Accordingly, although PII may be submitted, it is not solicited and therefore not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply.

For this collection, an annual report will have the same confidentiality requirements as a PMA application because it qualifies as a substitute for a manufacturer's submission submitted of a PMA. Confidentiality of information submitted to FDA under a premarket notification is governed by the provisions of 21 CFR part 20 and section 814.9, and is mandated. These provisions do not permit disclosure of information in a premarket notification submission that is trade secret or commercial confidential unless that information has been previously disclosed or as permitted under the Federal Freedom of Information Act. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. Information provided under this collection is handled in a manner to comply with the FDA regulations on public information in 21 CFR Part 20. Data will be kept private to the fullest extent allowed by law. These provisions do not permit disclosure of information in a premarket notification.

11. Justification for Sensitive Questions

This information collection does not include questions pertaining to sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Annual reporting for custom devices	34	1	34	40	1,360

Our estimate is based on 34 submissions received in 2019. We assume 40 hours is necessary to prepare the report and base this on the elements described and discussed in the guidance document.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Costs
Marketing Manager and Lawyer *	1,360	$71	$96,560

*Based on May 2019 wage estimates issued by the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm) for the "*Marketing Manager*" and "*Lawyer*" occupations (occupation codes 11-2021 and 23-1011, respectively). Therefore, FDA estimates the total annual reporting cost to industry for submissions of an annual report on custom devices is 1,360 total hours multiplied by $71 per hour equals $96,560. When divided by 34 submissions, this is an average of $2,840 per submission.

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Costs for review of annual reports for custom devices will be absorbed through existing resource allocations.

15. Explanation for Program Changes or Adjustments

The information collection reflects adjustment. We have increased the number of respondents from 33 to 34 to reflect more recent data.

16. Plans for Tabulation and Publication and Project Time Schedule

We do not intend to publish or tabulate the results of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.