U.S. Food and Drug Administration
Transfer of a Premarket Notification Clearance
OMB Control No. 0910-NEW

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This guidance provides information on how to notify FDA of the transfer of a 510(k) clearance from one holder to another, and the procedures FDA and industry should use to ensure public information in FDA's databases about the current 510(k) holder for a specific device(s) is accurate and up-to-date.

The Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85) amended section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by requiring domestic and foreign device establishments to begin submitting their registration and device listing information to FDA by electronic means rather than on paper forms,[1] and also specified the timeframes within which establishments are required to submit such information.[2] In accordance with FDAAA, the Agency launched FDA's Unified Registration and Listing System (FURLS), an Internet-based registration and listing system.[3]

Notification to FDA of a sale or other transfer of a 510(k) clearance, whether or not the device is already on the market, is accomplished by compliance with device listing requirements. As a result of the launch of the FURLS Device Registration and Listing Module (DRLM) and the changes to the registration and listing regulations that became effective on October 1, 2012,[4] the medical device listing information provided to FDA changed. Owners and operators of medical device establishments that market 510(k)-cleared devices must now supply the FDA-assigned premarket submission number of the cleared 510(k) when they list their devices in FURLS.[5] This listing allows FDA to easily identify the holder of each 510(k) based on the records created by manufacturers, specification developers, repackers/relabelers, single-use device reprocessors, or remanufacturers in FURLS DRLM. Listing information is required to be updated at least annually[6] and there may only be one 510(k) holder for a device at a time;[7] therefore, this updated listing provides FDA with current 510(k) holder information by 510(k) number.

The purpose of the guidance is to provide information on how to notify FDA of the transfer of a premarket notification clearance from one holder to another, and the procedures FDA and industry should use to ensure public information in FDA's

[1] See FD&C Act section 510(p) (21 U.S.C. § 360(p))
[2] See FD&C Act sections 510(b)(2), (i), and (j) (21 U.S.C. §§ 360(b)(2), (i), and (j)).
[3] See 77 FR 45927 (August 2, 2012).
[4] See id.
[5] See 21 CFR 807.25(g)(4).
[6] See FD&C Act section 510(j) (21 U.S.C. § 360(j)) and 21 CFR 807.22.
[7] See FD&C Act section 510(k) (21 U.S.C. § 360(k)) and 21 CFR 807.81(a).

databases about the current 510(k) holder for a specific device(s) is accurate and up-to-date.

2. Purpose and Use of the Information Collection

The information is collected from premarket notification (510(k)) clearance holders and parties claiming to be 510(k) holders who wish to voluntarily report a transfer of 510(k) clearance on FURLS, outside of the required listing reporting and the annual listing reporting requirement, or who submit 510(k) transfer documentation when more than one party lists the same 510(k).

Previously, FDA's databases did not reflect changes in the 510(k) holder that occurred after FDA's clearance of the 510(k). This was in part because 510(k) holders were not required to list their devices by 510(k) number, which made it difficult for FDA to tie a particular 510(k) to its current holder. Lack of updated, accurate 510(k) holder information created a number of challenges for FDA, for current 510(k) holders, future 510(k) submitters, and other stakeholders.

The information notifies FDA of the transfer of a premarket notification clearance from one holder to another and helps to ensure that the public information in FDA's databases about the current 510(k) holder for a specific device(s) is accurate and up-to-date.

Respondents to this information collection are private sector or other for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

Notification to FDA of a sale or other transfer of a 510(k) clearance is accomplished via compliance with listing requirements through use of FURLS, an Internet-based registration and listing system. Therefore, FDA estimates that 100 percent of the respondents will use electronic means to fulfill the agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. The Food and Drug Administration is the only Federal agency responsible for premarket review of medical devices, as well as medical device registration and listing. Respondents provide the information once per transfer of ownership of a premarket notification. Because 510(k) holders are required to register and list prior to marketing a device and to update their listing annually (see OMB control number 0910-0625) and would update information regarding the 510(k) holder at that time, the reporting of the transfer of ownership described in this ICR is voluntary and happens only upon the transfer of ownership and between annual reporting periods or when more than one party lists the same 510(k).

5. Impact on Small Businesses or Other Small Entities

The respondents to this collection of information are 510(k) holders and parties claiming to be 510(k) holders.

The Small Business Administration (SBA) considers medical device manufacturers to qualify as small businesses when they employ no more than a certain number of workers – these thresholds vary by NAICS codes (U.S. Small Business Administration , Table of Small Business Size Standards. (February 2016). https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf). Using the employment statistics from the 2012 Economic Census, we determine the number of medical device firms that may be considered small entities (U.S. Census Bureau. 2012. "2012 Economic Census of the United States (EC1231SA1) - Manufacturing: Subject Series: Location of Manufacturing Plants: Employment Size for Subsectors and Industries by U.S., State, County and Place." Retrieved July 2017 from https://factfinder.census.gov).[8] This analysis indicates that approximately 98-99 percent of medical device establishments qualify as small businesses according to the SBA criteria.

FDA aids small businesses in dealing with the regulations by providing guidance and information through CDRH's Division of International and Consumer Education (DICE). DICE provides technical and non-financial assistance to firms through a comprehensive program including seminars, educational conferences, printed and electronic information materials, and via e-mail and a toll-free telephone number. Other CDRH staff members are also available to respond to questions.

6. Consequences of Collecting the Information Less Frequently

   Respondents provide the information once per transfer of ownership of a premarket notification. Because 510(k) holders are required to register and list prior to marketing a device and to update their listing annually (see OMB control number 0910-0625) and would update information regarding the 510(k) holder at that time, the reporting of the transfer of ownership described in this ICR is voluntary and happens only upon the transfer of ownership and between annual reporting periods or when more than one party lists the same 510(k). There are no legal obstacles to reduce the burden.

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 12/22/2014 (79 FR 76331). No comments related to the information collection were received.

9. Explanation of Any Payment or Gift to Respondents

   No payment or gifts are provided to respondents of the information collection.

10. Assurance of Confidentiality Provided to Respondents

[8] The 2012 Economic Census measures establishment employment size in bands of 500-999, 1,000-2,499, and 2,500 employees or more. For the firms in NAICS categories that have SBA size standards of 750 or 1,250, we use a proportionate number of firms to determine the numerator. Regardless, any alternative calculation does not affect the rounded percentage result.

All information filed by a registrant is available for public inspection as required by 21 CFR 807.37. Information provided to, or obtained by, FDA is subject to release under the Freedom of Information Act (5 U.S.C. 552) and the implementing regulations contained in 21 CFR parts 20 and 21.

11. Justification for Sensitive Questions

The information collected does not include questions that are of a sensitive nature, such as, sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

This draft guidance is intended to provide information on how to notify FDA of the transfer of a 510(k) clearance from one person to another, and the procedures FDA and industry should use to ensure public information in FDA's databases about the current 510(k) holder for a specific device(s) is accurate and up-to-date. The proposed information collection seeks to provide information in order to notify FDA of the transfer of a premarket notification (510(k)) clearance.

The Agency estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Voluntary reporting of transfer of 510(k) Clearance on FDA's Unified Registration and Listing System (Outside of Annual Listing Reporting Requirement)	4,080	1	4,080	0.25	1,020
Submission of 510(k) transfer documentation when more than one party lists the same 510(k)	2,033	1	2,033	4	8,132
Total					9,152

Currently, FDA estimates 78% of 510(k)s are listed outside of the annual registration cycle based on numbers in the FURLS database from fiscal year 2009 through fiscal year 2014. Fiscal year 2008 was left out of this cohort as it was the first year that registrants were required to report the 510(k) number on their listings and, therefore, an unusually high number of listings were created. An average of 5,231 510(k)s have been listed in

each year since 2008. FDA estimates that annually 78% of 510(k)s will continue to be listed outside of the annual requirement. FDA estimates that 4,080 510(k)s may be listed outside of the annual registration cycle. FDA estimates that it will take approximately 15 minutes for each listing, for a total reporting burden of 1,020 hours.

FDA estimates it will have 2,033 instances of more than one party claiming to be a 510(k) holder for a specific device as part of annual registration and listing. The Agency reached this estimate by identifying the number of unique 510(k) device listings entered in FURLS between fiscal years 2009 and 2014 that conflict with a listing already entered by another party (5,304), dividing that number by the number of years (six), and multiplying by the average number of parties claiming to be the 510(k) holder when there is a conflict in the current FURLS database (2.3). The draft guidance identifies potential documentation a party could submit to FDA to establish the transfer of a 510(k) clearance. FDA estimates it will take a party approximately 4 hours to locate and submit information to establish the transfer of the 510(k) clearance, resulting in 8,132 burden hours for those 2,033 parties claiming to be 510(k) holders. FDA reached this estimate based on its expectation of the amount of time it will take a party to locate the information, to copy, and to submit a copy to FDA.

The burden estimate does not include the maintenance of records used to document transferring a premarket notification (510(k)) clearance. Based on available information, FDA believes that the maintenance of these records is a usual and customary part of normal business activities. For example, in the ordinary course of business, supporting documents should be kept to verify asset information for calculating the annual depreciation or calculating gain or loss on sale of an asset on a businesses' tax return. Therefore, this recordkeeping requirement creates no additional paperwork burden.

12b. Annualized Cost Burden Estimate

FDA estimates that the total estimated burden cost to industry relating to this information collection will be $658,944, which is the total number of burden hours expended, 9,152, multiplied by an average wage rate of $72 per hour.*

* Based on The Regulatory Affairs Professional Society (RAPS) average total annual compensation of $150,422 for a U.S. regulatory affairs professional (http://www.raps.org/uploadedFiles/Site_Setup/News_and_Trends/Research/2016/2016_SoP_Report.pdf, p.11). The hourly rate of $72 above assumes a 40-hour work week and is rounded to the nearest dollar.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs Professional	9,152	$72	$658,944

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

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

14. Annualized Cost to the Federal Government

FDA estimates approximately 1 full time equivalent (FTE) employee will review the information. Therefore, we estimate a cost of $306,800 (cost of an FTE to include benefits and overhead), based on our FY 2017 FDA Budget Request – Executive Summary – All Purpose Table.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The CDRH 510(k) database is publicly available. FDA has linked the 510(k) database to FURLS, which provides the most up to date information available on the current holder of a 510(k). By linking the CDRH 510(k) database to FURLS, FDA is using information from the FURLS database to provide the most up-to-date information available on the current holder of a 510(k).

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

The expiration date of OMB approval will be displayed in the guidance document.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.