

TABLE 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
866.5950 .....	Genetic Health Risk Assessment System .....	PTA	Exemption is limited to a genetic health risk assessment system that has received a first-time FDA marketing authorization (e.g., 510(k) clearance) for the genetic health risk assessment system (a “one-time FDA reviewed genetic health risk assessment system”).
876.1500 .....	Endoscopic Maintenance System .....	PUP	
880.6710 .....	Purifier, Water, Ultraviolet, Medical .....	KMG	
884.5960 .....	Vibrator for Therapeutic Use, Genital .....	KXQ	

**V. Reference**

The following reference is on display in the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>. FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA Guidance, “Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,” February 19, 1998, available at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf>.

Dated: October 31, 2017.

**Lauren Silvis,**  
Chief of Staff.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. FDA–2013–N–0618; FDA–2013–N–1155; FDA–2010–N–0118; FDA–2011–N–0655; FDA–2014–N–0086; FDA–2011–N–0144; FDA–2016–N–2836]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White

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**SUPPLEMENTARY INFORMATION:** The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Reporting and Recordkeeping for Electronic Products—General Requirements .....	0910–0025	7/31/2020
Food Labeling Regulations .....	0910–0381	7/31/2020
Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 .....	0910–0520	7/31/2020
Animal Generic Drug User Fee Act Cover Sheet .....	0910–0632	7/31/2020
Potential Tobacco Product Violations Reporting Form .....	0910–0716	7/31/2020
Voluntary Qualified Importer Program Guidance for Industry .....	0910–0840	7/31/2020
Donor Risk Assessment Questionnaire for the FDA/National Heart, Lung, and Blood Institute—Sponsored Transfusion-Transmissible Infectious Monitoring System .....	0910–0841	7/31/2020

Dated: November 2, 2017.

**Anna K. Abram,**  
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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