information collection request supporting the program expires on December 31, 2014. At this time, the burden for this information collection remains unchanged.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
558.6(a)(3) through (a)(5)	15,000	25	375,000	0.25 (15 minutes)	93,750
558.6(d)(1)(i) through (d)(1)(iii)	300	1	300	0.25 (15 minutes)	75
558.6(d)(1)(iv)	20	1	20	0.25 (15 minutes)	5
558.6(d)(2)	1,000	5	5000	0.25 (15 minutes)	1,250
514.1(b)(9)	1	1	1	3.00	3
Total					95,083

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2 —ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
558.6(c)(1) through (c)(4)	112,500	10	1,125,000	0.0167 (1 minute)	18,788
558.6(e)(1) through (e)(4)	5,000	75	375,000	0.0167 (1 minute)	6,263
Total					25,051

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of time required for record preparation and maintenance is based on Agency communication with industry and Agency records and experience.

Dated: September 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22808 Filed 9–24–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1344]

Policy Clarification for Fluoroscopic Equipment Requirements; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Policy Clarification for Fluoroscopic Equipment Requirements.'' This draft guidance describes FDA's intent to clarify the application of certain aspects of the performance standard requirements for fluoroscopic equipment when manufacturers comply with certain International Electrotechnical Commission (IEC) standards. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 24, 2014.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Policy Clarification for Fluoroscopic Equipment Requirements'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Donald Miller, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4646, Silver Spring, MD 20993–0002, 301–796–3299.

SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance document, ''Policy Clarification for Fluoroscopic Equipment Requirements'' was developed to describe FDA's intent to clarify the application of certain aspects of the performance standard requirements in 21 CFR 1020.32 for fluoroscopic equipment when the manufacturer has complied with certain IEC standards. FDA believes that a declaration of conformity with the applicable IEC standard and the applicable measure(s) set forth in this guidance as part of the 510(k) submission for their device will sufficiently address the concerns intended to be addressed by certain parts of the requirements of § 1020.32, such that the public health is adequately protected.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will

represent the Agency's current thinking on the policy clarification for certain fluoroscopic equipment requirements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Policy Clarification for Fluoroscopic Equipment Requirements'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1806 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E are currently approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 1020 have been approved under OMB control number 0910–0025.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: September 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22806 Filed 9–24–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–M–0326, FDA–2013–M–1324, FDA–2013–M–1693, FDA–2014–M–0069, FDA–2014–M–0166, FDA–2014–M–0167, FDA–2014–M–0224, and FDA–2014–M–0254]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–6570.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from January 1, 2014, through March 31, 2014, and includes one denial action during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2014, THROUGH MARCH 31, 2014

PMA No., Docket No.	Applicant	Trade name	Date of action
P070023, FDA–2013–M–1324	Fzio Med, Inc	Oxiplex®/SP Gel	Denied October 21, 2013.
P110016/S008, FDA–2013–M–1693	St. Jude Medical, Inc	Therapy Cool Flex Ablation Catheter	Approved December 18, 2013.
P130004, FDA–2014–M–0069	Ocular Therapeutics, Inc	ReSure® Sealant	Approved January 8, 2014.
P130021, FDA–2014–M–0166	Medtronic CoreValve LLC	Medtronic CoreValve™ System	Approved January 17, 2014.
P100040/S012, FDA–2014–M–0167	Medtronic Vascular	Valiant Thoracic Stent Graft with Captivia Delivery System.	Approved January 22, 2014.
P120005/S002, FDA–2014–M–0224	Dexcom, Inc	Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System.	Approved February 3, 2014.