

request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer’s 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer’s documented review and recommendation, to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually 3 years. The 3P510k review program is intended to allow review of devices by third-party 510k review organizations (3PROs) to provide manufacturers of these devices an alternative review process that allows FDA to best utilize our resources on higher risk devices.

Respondents to this information collection are businesses or government and can be for-profit or not-for-profit organizations, such as third party review organizations.

The guidance “510(k) Third-Party Review Program, Guidance for Industry, Food and Drug Administration Staff and Third Party Review Organizations” (March 2020) was intended to provide a comprehensive look into FDA’s current thinking regarding the 3P510k program and third party review of Emergency Use Authorization (EUA) requests by describing FDA’s expectations for the review of 510(k) submissions and EUA requests by third party review organizations. This guidance document also reflects section 523 of the FD&C Act, which directs FDA to issue guidance on the factors that will be used in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person. This guidance was superseded on November 21, 2024, when FDA issued the final guidance “510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review; Guidance

for Industry, Food and Drug Administration Staff, and Third Party Review Organizations” (November 2024) (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program-and-third-party-emergency-use-authorization-eua-review>). The guidance also includes new content that outlines how FDA may contract with third party review organizations to perform reviews of EUA requests (3PEUA review) when appropriate emergency declaration authorities are active under section 564 of the FD&C Act. (See OMB Control Number 0910–0595.)

In the **Federal Register** of July 3, 2025 (90 FR 29552), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity; guidance document section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests for accreditation (initial); Section V.D	1	1	1	40	40
Requests for accreditation (re-recognition); Section V. D	3	1	3	24	72
510(k) reviews conducted by 3PROs; Section V. B	9	14	126	40	5,040
Complaints; Section V.C	1	1	1	0.25 (15 minutes)	0.25
Total					5,152.25

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity; guidance document section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
510(k) reviews conducted by 3PROs; Section V. B	9	14	126	10	1,260
Records regarding qualifications to receive FDA recognition as a 3PRO; Section V. C	9	1	9	1	9
Recordkeeping system regarding complaints; Section V. C	9	1	9	2	18
Total					1,287

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

Upon review of this information collection, we have adjusted our burden estimate for the average burden hours required per response for initial requests for accreditation from 24 to 40 hours to more accurately reflect the time required based on recent experience of FDA program staff. This adjustment has resulted in an increase of 15 hours to the currently approved burden.

Lowell M. Zeta,
Acting, Deputy Commissioner for Policy, Legislation, and International Affairs.
[FR Doc. 2025–20772 Filed 11–21–25; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–5139; FDA–2024–E–5140; FDA–2024–E–5141]

Determination of Regulatory Review Period for Purposes of Patent Extension; ENVISION MAMMOGRAPHY PLATFORM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period

for ENVISION MAMMOGRAPHY PLATFORM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by January 23, 2026. Furthermore, any interested person may

petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 26, 2026. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 23, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket Nos. FDA–

2024–E–5139; FDA–2024–E–5140; and FDA–2024–E–5141 for Determination of Regulatory Review Period for Purposes of Patent Extension; ENVISION MAMMOGRAPHY PLATFORM.

Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Jack Dan, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250,

Silver Spring, MD 20993, 240–402–6940.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device ENVISION MAMMOGRAPHY PLATFORM. ENVISION MAMMOGRAPHY PLATFORM is indicated for introduction of Envision Mammography Platform that include updated gantry with adjustable tilted C-Arm, detector electronics, user interfaces, anti-scatter grid, dynamic collimator, and introduction of X-ray source with moving focal spot. Subsequent to this approval, the USPTO received patent term restoration applications for ENVISION MAMMOGRAPHY PLATFORM (U.S. Patent No. 8,457,282; 8,767,911; and 9,895,115) from Hologic, Inc., and the USPTO requested FDA’s assistance in determining these patents’ eligibility for patent term restoration. In a letter dated March 17, 2025, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of

ENVISION MAMMOGRAPHY PLATFORM represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ENVISION MAMMOGRAPHY PLATFORM is 310 days. Of this time, 0 days occurred during the testing phase of the regulatory review period, while 310 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective: not applicable.* The applicant claims that the length of the testing phase of the regulatory review period is 0 days.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* August 31, 2023. FDA has verified the applicant's claim that the premarket approval application (PMA) for ENVISION MAMMOGRAPHY PLATFORM (PMA P080003/S009) was initially submitted August 31, 2023.

3. *The date the application was approved:* July 5, 2024. FDA has verified the applicant's claim that PMA P080003/S009 was approved on July 5, 2024.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,163, or 1,198 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA

investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–20667 Filed 11–21–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–E–5681]

Determination of Regulatory Review Period for Purposes of Patent Extension; ALTIUS DIRECT ELECTRICAL NERVE STIMULATION SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ALTIUS Direct Electrical Nerve Stimulation System and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by January 23, 2026. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 26, 2026. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late,

untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 23, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

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- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2024–E–5681 for Determination of Regulatory Review Period for Purposes of Patent Extension; ALTIUS DIRECT ELECTRICAL NERVE STIMULATION SYSTEM. Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly