4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-D-1242]

Animal Studies for Dental Bone Grafting Material Devices--Premarket Notification (510(k)) Submissions; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Animal Studies for Dental Bone Grafting Material Devices--Premarket Notification (510(k)) Submissions." This guidance document provides recommendations for animal study design and animal study information to include to support a 510(k) submission for dental bone grafting material devices. This guidance may help manufacturers comply with some special controls for dental bone grafting material devices. The recommendations reflect current review practices and are intended to promote consistency and facilitate efficient review of these submissions.

DATES: The announcement of the guidance is published in the *Federal Register* on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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 No. FDA-2024-D-1242 for "Animal Studies for Dental Bone Grafting Material Devices––Premarket Notification (510(k)) Submissions." Received comments 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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 guidance document entitled "Animal Studies for Dental Bone Grafting Material Devices--Premarket Notification (510(k)) Submissions" to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD

20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Joel Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G234, Silver Spring, MD 20993-0002, 301-796-6520.

SUPPLEMENTARY INFORMATION:

I. Background

A dental bone grafting material device is a material that is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region. This guidance document provides premarket notification (510(k)) submission recommendations for animal studies that may help manufacturers comply with the in vivo performance special control identified in FDA's guidance, "Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices" (https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/dental-bone-grafting-material-devices-class-ii-special-controls-guidance-industry-and-fda-staff), for dental bone grafting material devices. This guidance document also provides recommendations for manufacturers who choose to combine an animal study that evaluates in vivo safety and performance of the dental bone grafting material with a biocompatibility evaluation of the implantation endpoint (or the local effects after implantation) to help reduce the total number of animals used to support the 510(k) submission. The recommendations reflect current review practices and are intended to promote consistency and facilitate efficient review of these submissions.

A notice of availability of the draft guidance appeared in the *Federal Register* of March 29, 2024 (89 FR 22160). FDA considered comments received and revised the guidance as appropriate in response to the comments, including minor clarifications to the animal study design recommendations for the evaluation of dental bone grafting material devices and providing additional reference citations.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Animal Studies for Dental Bone Grafting Material Devices--Premarket Notification (510(k)) Submissions." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the 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 https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products. This guidance document is also available at https://www.regulations.gov and https://www.fda.gov/regulatory-information/search-fda-guidance-documents. Persons unable to download an electronic copy of "Animal Studies for Dental Bone Grafting Material Devices--Premarket Notification (510(k)) Submissions" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUI00007042 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in the following table have been approved by OMB:

21 CFR Part or Guidance	Topic	OMB Control No.
807, subpart E	Premarket notification	0910-0120
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program"	Q-submissions and Early Payor Feedback Request Programs for Medical Devices	0910-0756

58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies	0910-0119

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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