Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 888.3041 to subpart D to read as follows:

§ 888.3041 Absorbable metallic bone fixation fastener.

(a) *Identification.* An absorbable metallic bone fixation fastener is an implant, such as a bone screw, pin, or Kirschner wire, composed of one or more absorbable metal or metal alloys and intended to provide rigid bone fixation suitable for osteosynthesis. The device is designed to fully absorb after osteosynthesis is achieved.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical data must demonstrate that the device performs as intended under the anticipated conditions of use. The absorption profile must be characterized to completion (full absorption). The difficulty of any revision surgeries must be documented.

(2) Non-clinical performance testing must demonstrate that the product performs as intended under anticipated conditions of use. Testing must:

(i) Evaluate the complete degradation profile of the device;

(ii) Evaluate the initial mechanical performance; and

(iii) Evaluate the mechanical performance as the device degrades.

(3) The device must be demonstrated to be biocompatible.

(4) The device must be demonstrated to be non-pyrogenic.

(5) Performance data must demonstrate the sterility of the device.

(6) Performance data must support the labeled shelf-life of the device by demonstrating continued sterility, package integrity, and device functionality (*i.e.,* degradation profile and mechanical performance) over the established shelf life.

(7) Labeling must include:

(i) Material composition;

(ii) Absorption byproducts;

(iii) A detailed summary of the product's technical parameters;

(iv) An expiration date/shelf life;

(v) Instructions for revision surgery;

(vi) Time to complete absorption; and

(vii) A summary of clinical data with the device.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–11302 Filed 6–4–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2026–N–5195]

Medical Devices; Orthopedic Devices; Classification of the Resorbable Calcium Salt Bone Void Filler Containing a Single Approved Aminoglycoside Antibacterial

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the resorbable calcium salt bone void filler containing a single approved aminoglycoside antibacterial into class II (special controls). The special controls that apply to the product type are identified in this order and will be part of the codified language for classification of the resorbable calcium salt bone void filler containing a single approved aminoglycoside antibacterial. We are taking this action because we have determined that classifying the product into class II will provide a reasonable assurance of safety and effectiveness of the product. We believe this action will also enhance patients' access to beneficial innovative products, in part by reducing regulatory burdens.

DATES: This order is effective June 5, 2026. The classification was applicable on May 17, 2022.

FOR FURTHER INFORMATION CONTACT: Aric Kaiser, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4518, Silver Spring, MD 20993–0002, 301–796–6425, *Aric.Kaiser@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the resorbable calcium salt bone void filler containing a single approved aminoglycoside antibacterial into class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness of the product. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the product into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally

marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On September 28, 2021, FDA received BONESUPPORT AB's request for De Novo classification of CERAMENT G. FDA reviewed the request in order to classify the product under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the product can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the product.

Therefore, on May 17, 2022, FDA issued an order to the requester classifying the product into class II. In this final order, FDA is codifying the classification of the product by adding 21 CFR 888.3046.[1] We have named the generic type of product ''resorbable calcium salt bone void filler containing a single approved aminoglycoside antibacterial,'' and it is identified as a resorbable implant intended to fill bony defects of the extremities where there is an increased risk of infection. It is intended to resorb over time and be replaced by new bone. The product is intended for reduction of recurrence of chronic osteomyelitis of long bones. It is not intended to treat infection.

FDA has identified the risks to health associated with this type of product and the measures required to mitigate these risks in table 1.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR RESORBABLE CALCIUM SALT BONE VOID FILLER CONTAINING A SINGLE APPROVED AMINOGLYCOSIDE ANTIBACTERIAL

Identified risks to health	Mitigation measures
Recurring or persistent or new infection	Clinical performance testing; Animal performance testing; Non-clinical performance testing; Product characterization, including drug substance; Antimicrobial susceptibility testing; Container compatibility testing; Sterilization validation; Stability and shelf life testing; Drug quality attribute performance testing; Pharmaceutical manufacturing information; and Aminoglycoside antibacterial approval.
Adverse tissue reaction	Clinical performance testing; Animal performance testing; Biocompatibility evaluation; and Pharmaceutical manufacturing information.
Antimicrobial resistance	Antimicrobial susceptibility testing; Antimicrobial resistance analysis; and Labeling.
Transient electrolyte imbalance (*e.g.,* hyperkalemia, hypercalcemia, or hypocalcemia).	Clinical performance testing; Animal performance testing; and Labeling.
Incomplete bone formation or lack of bone formation	Clinical performance testing; Animal performance testing; Postmarket surveillance; and Labeling.
Pathologic fracture	Clinical performance testing; Animal performance testing; and Labeling.
Product migration or extrusion	Clinical performance testing, Animal performance testing; and Labeling.
Drug-induced toxicity (*e.g.,* nephrotoxicity and ototoxicity)	Clinical performance testing; Animal performance testing; Product characterization, including drug substance; Drug quality attribute performance testing; Pharmaceutical manufacturing information; and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness of the product. For a product to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order. FDA supports the principles of the ''3Rs,'' to replace, reduce, and/or refine animal use in testing when feasible. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

Under the FD&C Act, submission of a premarket notification under section

[1] FDA notes that the **ACTION** caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the **Federal Register** Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for resorbable calcium salt bone void fillers containing a single approved aminoglycoside antibacterial. This product is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. 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. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 4, regarding combination products, have been approved under OMB control number 0910–0523; the collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139; and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 888.3046 to subpart D to read as follows:

§ 888.3046 Resorbable calcium salt bone void filler containing a single approved aminoglycoside antibacterial.

(a) *Identification.* A resorbable calcium salt bone void filler containing a single approved aminoglycoside antibacterial is a resorbable implant intended to fill bony defects of the extremities where there is an increased risk of infection. It is intended to resorb over time and be replaced by new bone. The product is intended for reduction of recurrence of chronic osteomyelitis of long bones. It is not intended to treat infection.

(b) *Classification.* Class II (special controls). The special controls for this product are:

(1) Clinical performance testing must demonstrate that the product performs as intended under anticipated conditions of use. Clinical testing must evaluate recurrence of chronic osteomyelitis of long bones. Testing must describe safe aminoglycoside serum levels below toxic concentrations. Imaging data (*e.g.,* radiographs) must evaluate product resorption and new bone formation at the location where the product has been placed.

(2) Animal performance testing must demonstrate that the product performs as intended under anticipated conditions of use. Testing must include the following:

(i) Testing must characterize the performance of the product in an appropriate animal model. The model must mimic the identified clinical use, *e.g.,* in a large animal infection model of osteomyelitis. Testing must characterize aminoglycoside serum levels and characterize product resorption and replacement by new bone, including the characterization of the rates of product resorption and new bone formation over clinically relevant timeframes.

(ii) Testing must be conducted in a relevant animal model to evaluate the pharmacology and toxicology of the final, finished product.

(3) Non-clinical performance testing must demonstrate that the product performs as intended under anticipated conditions of use. Testing must characterize the product in appropriate in vitro models.

(i) Elution kinetics studies must be conducted to determine the in vitro drug release profile of the aminoglycoside from the product lot(s) used for the clinical performance testing studies.

(ii) Dissolution testing must characterize the resorption profile of the product.

(iii) The following physical and chemical properties must be characterized for in situ setting products:

(A) Setting pH and reaction temperature;

(B) Setting and working times;

(C) Force required to transfer the product from the mixing container to the site of action;

(D) Chemical composition of the in vivo-cured product; and

(E) Dimensional stability of the in vivo-cured product.

(4) Characterization of the product, including the drug substance and drug constituent part components (as applicable), must demonstrate that critical quality attributes and specifications, including compendial requirements, are met and must include:

(i) Identification of, and justification for, the specification for each individual component (including the drug substance) of the drug constituent part of the product.

(ii) Confirmation that the specifications for the aminoglycoside and drug constituent part components (if present) conform to any corresponding United States Pharmacopeia (USP) monographs. In addition, the aminoglycoside specification must also include other tests that ensure the quality of the product. These tests may, for example, include appearance, solubility, identification, related substances, ratios of active components, assay measured using high performance liquid chromatography, or potency measured using a bioassay.

(iii) Identification of, and justification for, the product specification(s) to be met on release of each batch and on stability, including description, identification, aminoglycoside assay, in vitro elution, degradation products, elemental impurities, content uniformity, residual solvents, sterility, and endotoxin. If the aminoglycoside is prepared as a solution before mixing with the other components, that specification must include appearance, pH, and particulates.

(iv) Identification of, and justification for, the specifications that apply to the freshly mixed product (pre-setting configuration) and the mixed product administered from the mixing device/device constituent part and allowed to set over a specified time (post-setting

configuration). For in vitro elution/drug release specifications, the acceptance criteria must include data from the product lot(s) used in clinical performance (or equivalent) studies.

(A) The specification must include tests adequate to ensure the quality attributes of the pre-setting configuration considering the product design, including but not limited to, tests for appearance, setting time, and injectability or extrusion force.

(B) The specification must include tests adequate to ensure the quality attributes of the post-setting configuration considering the product design, including but not limited to, tests for appearance, aminoglycoside assay, aminoglycoside degradants, aminoglycoside elution/drug release, uniformity, sterility, endotoxins, setting reaction temperature, working time, and usable amount of the product.

(v) For the specifications noted in paragraphs (b)(4)(i) through (b)(4)(iv) of this section, a description of the analytical procedures and a summary of the analytical procedures development and validation must be provided. For in vitro elution/drug release specifications, data must be provided to demonstrate method adequacy, *e.g.,* in terms of discriminating power for changes/differences in critical quality attributes that could impact product performance, stability-indicating potential, and/or in vitro-in vivo correlation.

(5) An analysis must be provided that identifies and evaluates any contribution to the development and spread of antimicrobial resistance.

(6) Susceptibility testing to the aminoglycoside must be conducted for all bacterial isolates identified during the clinical performance testing specified in paragraph (b)(1) of this section.

(7) If FDA determines that the clinical performance testing specified in special control (b)(1) of this section is insufficient to evaluate long-term safety of the product, post-market surveillance (PMS) must evaluate new bone formation at the location where the product has been placed in accordance with an FDA-agreed upon protocol.

(8) The product, including the delivery device constituent part(s) (*e.g.,* delivery syringes) and patient-contacting surgical instruments, must be demonstrated to be biocompatible.

(9) The product and each of its components (*i.e.,* aminoglycoside and the drug constituent part components (if present)) must be demonstrated to be compatible with their respective commercial container closure system/packaging.

(10) Performance data must support the sterility and pyrogenicity of the product. The performance data must confirm that the sterilization process has no significant adverse impact (*e.g.,* the generation of new degradants) on the drug quality attributes (*e.g.,* assay, elution) of the product.

(11) Performance data must support the claimed expiration dating period/shelf life by demonstrating continued sterility, stability (see paragraph (b)(12)(ii) of this section), package integrity, and product functionality over the identified expiration/shelf life. Data to demonstrate continued sterility, stability, and package integrity must be collected for each component and the final, finished product. In addition, product functionality must be demonstrated for the final finished product. Extension of the expiration/shelf life must be submitted in a premarket notification and supported by the data described in this paragraph.

(12) Performance data from testing batches at release and on stability must characterize the drug quality attributes of the final, finished product (see paragraph (b)(4) of this section), demonstrate product specifications are consistently met, and support the claimed expiration/shelf-life date. This information must include the following:

(i) Batch Release Testing: Batch release data on multiple lots of the final, finished product manufactured using the proposed commercial process must demonstrate that specifications for each component and the final, finished product are met. Data on multiple lots of the mixed product (pre- and post-setting) obtained when the final, finished product is used according to the directions in the instructions for use must demonstrate that the pre- and post-setting specifications are met.

(ii) Stability Testing: The final, finished product manufactured using the proposed commercial process and in the proposed commercial packaging must be stored under tightly controlled conditions and periodically tested to demonstrate the stability of the drug constituent part (all components) and the final, finished product. In addition, at each pre-determined stability time point the product must meet the pre- and post-setting specifications. Testing must include three batches placed under long-term storage and accelerated stability conditions and then one batch placed on long-term stability each year. Testing must verify that the acceptance criteria for each specification are met at each stability time point. Parameters that are not expected to change on stability, *e.g.,* elemental impurities, only need to be tested at batch release, and a justification must be provided.

(13) Pharmaceutical manufacturing information must be provided, and appropriate documentation be available on inspection or if requested by FDA, for the drug constituent part and the final, finished product to demonstrate that the production processes are properly developed, conducted, controlled, and monitored. This information must include the following:

(i) A description of the manufacturing process and controls, including in-process controls, to ensure consistent quality. Such information may be provided by reference to a drug master file (DMF).

(ii) A description of the commercial batch formula, including the quality standard (*e.g.,* USP/National Formulary) to be met for each excipient, and representative Certificates of Analysis (COAs) for excipients to confirm quality.

(iii) Information or reference to one or more DMFs regarding the drug substance to understand the impurity profile, and representative COAs for the drug substance to confirm quality.

(iv) Identification and qualification of in-process hold times for the drug constituent part, where applicable.

(v) A description of how compliance with the current good manufacturing practice (CGMP) requirements is achieved at the facilities manufacturing the drug constituent part and final, finished product. This includes identification of the activities that occur at each site, and for any facilities for which § 211 of this chapter is not the established CGMP operating system, a description of how the facilities perform the responsibilities related to the subset of § 211 requirements established in § 4 subpart A of this chapter.

(14) The product must contain a single approved aminoglycoside antibacterial.

(15) Labeling must include the following:

(i) Identification of the maximum volume of the product that may be safely implanted;

(ii) A detailed summary of the product's technical parameters;

(iii) An expiration date/shelf life;

(iv) A list of probable adverse events associated with the use of the product, including those observed during clinical performance studies;

(v) Warning about the risk of antimicrobial resistance and the risk of systemic adverse effects from the aminoglycoside;

(vi) Precaution against implanting into patients with calcium metabolism issues; overfilling; adding other

substances other than those provided (in absence of data on the use of the product mixed with other substances); overpressuring the product because this may lead to extrusion of the product beyond the site of its intended application and damage to surrounding tissues, and since this may lead to fat embolization or embolization of the product material into the bloodstream; and disturbing the product (over a specific time frame) once it begins to harden;

(vii) Instructions about proper placement and containment in the desired treatment area; adequate fixation (as necessary); product working time and setting time with any special instructions with respect to drying the surgical field and/or not irrigating the defect site prior to final setting of the product (for a product intended to set in vivo); how and when excess material should be removed from the defect site;

(viii) When available, and according to the timeframe included in the PMS protocol agreed upon with FDA as specified in paragraph (b)(7) of this section, a detailed summary of the PMS data must be provided, including:

(A) Updates to the labeling to accurately reflect outcomes or necessary modifications based upon data collected during the PMS experience; and

(B) Inclusion of results and adverse events associated with utilization of the product during the PMS.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–11308 Filed 6–4–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2026–N–5830]

Medical Devices; Orthopedic Devices; Classification of the Shoulder Joint Humeral (Hemi-Shoulder) Ceramic Head/Metallic Stem Cemented or Uncemented Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the shoulder joint humeral (hemi-shoulder) ceramic head/metallic stem cemented or uncemented prosthesis into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the shoulder joint humeral (hemi-shoulder) ceramic head/metallic stem cemented or uncemented prosthesis. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective June 5, 2026. The classification was applicable on December 16, 2022.

FOR FURTHER INFORMATION CONTACT: Joseph Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4566, Silver Spring, MD 20993–0002, 240–402–4210, *Joseph.Russell@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the shoulder joint humeral (hemi-shoulder) ceramic head/metallic stem cemented or uncemented prosthesis into class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less