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

burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

For this device, FDA issued an order on April 30, 2020, finding the Tornier Pyrocarbon Humeral Head not substantially equivalent to a predicate not subject to PMA. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

On February 8, 2022, FDA received Tornier SAS's request for De Novo classification of the Tornier Pyrocarbon Humeral Head device. FDA reviewed the request in order to classify the device 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 device 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 device.

Therefore, on December 16, 2022, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 888.3695.[1] We have named the generic type of device ''shoulder joint humeral (hemi-shoulder) ceramic head/metallic stem cemented or uncemented prosthesis,'' and it is identified as a device using a replacement humeral head made of ceramic materials such, as pyrolytic carbon, and a stem made of alloys, such as cobalt-chromium-molybdenum. It is intended to be implanted to replace the articular surface of the proximal end of the humerus and to be fixed with or without bone cement (21 CFR 888.3027). This device is not intended for use in total shoulder arthroplasty.

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

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR SHOULDER JOINT HUMERAL (HEMI-SHOULDER) CERAMIC HEAD/METALLIC STEM CEMENTED OR UNCEMENTED PROSTHESES

Identified risks to health	Mitigation measures
Adverse events of the index shoulder including pain, unanticipated adverse device effects, subsequent surgical interventions, wear of the native bone, osteolysis, loosening and migration, and revision including revision due to device wear, component dissociation, or device brittle fracture.	Clinical data; Non-clinical performance testing; and Biocompatibility evaluation
Adverse tissue reaction due to • Device materials. • Fretting and corrosion. • Wear particulates.	Biocompatibility evaluation; and Non-clinical performance testing.
Infection	Sterilization validation; Reprocessing validation; Shelf life testing; Pyrogenicity testing; and Labeling.
Insufficient range of motion	Non-clinical performance testing.

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 device. For a device 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.

Under the FD&C Act, submission of a premarket notification under section 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 shoulder joint humeral (hemi-shoulder) ceramic head/metallic stem cemented or uncemented prostheses. This device 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; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

[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.

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 § 888.3695 to subpart D to read as follows:

§ 888.3695 Shoulder joint humeral (hemi-shoulder) ceramic head/metallic stem cemented or uncemented prosthesis.

(a) *Identification.* A shoulder joint humeral (hemi-shoulder) ceramic head/metallic stem cemented or uncemented prosthesis is a device using a replacement humeral head made of ceramic materials such, as pyrolytic carbon, and a stem made of alloys, such as cobalt-chromium-molybdenum. It is intended to be implanted to replace the articular surface of the proximal end of the humerus and to be fixed with or without bone cement (§ 888.3027). This device is not intended for use in total shoulder arthroplasty.

(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 anticipated conditions of use and include the following:

(i) Evaluation of improvement of shoulder function and reduction of symptoms, including pain and function, for the indications for use; and

(ii) Evaluation of adverse events, including pain, unanticipated adverse device effects, subsequent surgical interventions, wear of the native bone, osteolysis, loosening and migration, and revision, including revision due to device wear, component dissociation, or device brittle fracture.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:

(i) Evaluation of the mechanical function (mechanical fatigue strength including evaluation of fretting and corrosion, static mechanical strength, modular component disassembly strength, and wear analysis) and durability of the implant; and

(ii) Evaluation of worst-case device range of motion.

(3) All patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must support the sterility and pyrogenicity of the device components intended to be sterile.

(5) Performance data must validate the reprocessing instructions for the reusable components of the device.

(6) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(7) Labeling must include the following:

(i) Validated methods and instructions for reprocessing of any reusable components; and

(ii) A shelf life.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–11306 Filed 6–4–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2026–0291]

RIN 1625–AA08

Special Local Regulation; Genesee River, Rochester, NY

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation (SLR) for certain navigable waters of the Genesee River. The SLR is needed to protect personnel and vessels from potential hazards created by the Rochester, NY Harborfest Water Ski Show on June 20, 2026. This regulation prohibits persons and vessels from being in the regulated area unless specifically authorized by the Captain of the Port, Sector Eastern Great Lakes or their designated representative.

DATES: This rule is effective from 11:45 a.m. until 5:30 p.m. on June 20, 2026.

ADDRESSES: To view available documents go to *https://www.regulations.gov* and search for USCG–2026–0291.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact MST1 Ori Martinez, Sector Eastern Great Lakes Waterways Management Division, U.S. Coast Guard; telephone 716–818–7693, or email *D09-SMB-SECBuffalo-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
SLR Special Local Regulation
U.S.C. United States Code

II. Background and Authority

An organization notified the Coast Guard that they will be holding two water ski shows on the Genesee River near Rochester, NY, on June 20, 2026. Hazards from water ski shows include watercraft and water skiers performing high speed maneuvers and multiple waterway obstructions used to enhance and protect the show.

The Captain of the Port Sector Eastern Great Lakes (COTP) is issuing this Special Local Regulation (SLR) under the authority in 46 U.S.C. 70041. The COTP has determined that potential hazards associated with the show are a safety concern for anyone within the regulated area. The purpose of this rulemaking is to protect event participants, non-participants, and transiting vessels before, during, and after the scheduled event.

Because of these potential hazards, the Coast Guard is issuing this rule without prior notice and comment. As is authorized by 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. We must establish this SLR by June 20, 2026, to protect personnel and vessels. Therefore, we do not have enough time to solicit and respond to comments.

For the same reasons, the Coast Guard finds that under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Discussion of the Rule

This rule establishes a temporary SLR from 11:45 a.m. until 5:30 p.m. on June 20, 2026. The regulated area would cover all navigable waters encompassing the show event area and require vessels transiting around the special regulated area to operate at a no wake speed. No vessel or person would be permitted to enter the regulated area without obtaining permission from the COTP or their designated representative.