December 16, 2022

Tornier SAS
℅ Lisa Stahl
Principal Regulatory Affairs Specialist
Tornier, Inc.
10801 Nesbitt Avenue South
Bloomington, Minnesota 55437

Re: DEN220012
Trade/Device Name: Tornier Pyrocarbon Humeral Head
Regulation Number: 21 CFR 888.3695
Regulation Name: Shoulder joint humeral (hemi-shoulder) ceramic head / metallic stem cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: QKW
Dated: February 7, 2022
Received: February 8, 2022

Dear Lisa Stahl:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Tornier Pyrocarbon Humeral Head, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Tornier Pyrocarbon Humeral Head associated with the Tornier Flex Stem is indicated for use as a replacement of deficient humeral heads disabled by:
> - Non-inflammatory degenerative joint diseases (osteoarthritis, avascular necrosis)
> - Traumatic arthritis.
>
> The Tornier Pyrocarbon Humeral Head Shoulder Prosthesis, combined with the Tornier Flex Humeral Stem, are to be used only in patients with an intact or reconstructable rotator cuff and if the native glenoid surface is intact or sufficient, where they are intended to increase mobility, stability, and relieve pain.
>
> Note: The coated humeral stem is intended for cemented or cementless use. The non-coated humeral stem is for cemented use only.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product,

contact CDRHProductJurisdiction@fda.hhs.gov. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Tornier Pyrocarbon Humeral Head, and substantially equivalent devices of this generic type, into Class II under the generic name shoulder joint humeral (hemi-shoulder) ceramic head / metallic stem cemented or uncemented prosthesis.

FDA identifies this generic type of device as:

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

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on April 30, 2020 automatically classifying the Tornier Pyrocarbon Humeral Head in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II.

On February 8, 2022, FDA received your De Novo requesting classification of the Tornier Pyrocarbon Humeral Head. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Tornier Pyrocarbon Humeral Head into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the Tornier Pyrocarbon Humeral Head can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

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 Biocompatibility evaluation
Adverse tissue reaction due to • Device materials • Fretting and corrosion • Wear particulates	Biocompatibility evaluation Non-clinical performance testing
Infection	Sterilization validation Reprocessing validation Shelf-life testing Pyrogenicity testing Labeling
Insufficient range of motion	Non-clinical performance testing

In combination with the general controls of the FD&C Act, the shoulder joint humeral (hemi-shoulder) ceramic head / metallic stem cemented or uncemented prosthesis is subject to the following special controls:

1. Clinical data must demonstrate that the device performs as intended under anticipated conditions of use and include the following:
    a. Evaluation of improvement of shoulder function and reduction of symptoms, including pain and function, for the indications for use; and
    b. 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:
    a. 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
    b. 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:
    a. Validated methods and instructions for reprocessing of any reusable components; and

b. A shelf-life.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the shoulder joint humeral (hemi-shoulder) ceramic head / metallic stem cemented or uncemented prosthesis they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Joseph Russell at 240-402-4210.

Sincerely,

Raquel A. Peat -S

CAPT Raquel Peat, Ph.D., M.P.H., USPHS
Director
OHT6: Office of Orthopedic Devices
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