Tornier, Inc.
% Lisa Stahl
Principal Specialist, Regulatory Affairs
10801 Nesbitt Ave. South
Bloomington, Minnesota 55437

October 26, 2021

Re: K213124
Trade/Device Name: Tornier Perform™ Reversed Glenoid Cannulated Glenospheres
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: September 24, 2021
Received: September 27, 2021

Dear Lisa Stahl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Michael Owens
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213124

Device Name
Tornier Perform™ Reversed Glenoid Cannulated Glenospheres

Indications for Use *(Describe)*
The Tornier Perform Reversed Glenoid Cannulated Glenospheres are indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle and with massive and non-repairable rotator cuff-tear with pain disabled by:
• Rheumatoid arthritis
• Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
• Correction of functional deformity
• Fractures of the humeral head
• Traumatic arthritis
• Revision of the devices if sufficient bone stock remains
Notes:
• All components are single use.
• The glenoid sphere implant is anchored to the bone with screws and is for non-cemented fixation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Date Prepared: October 25, 2021

Administrative Information

Name:	Tornier, Inc.
Address:	10801 Nesbitt Avenue South Bloomington, MN 55437 United States of America
Contact Person:	Lisa Stahl
Title:	Principal Specialist, Regulatory Affairs
Phone:	612-849-9970
Fax:	952-426-7601

Device Information

Name of Device:	Tornier Perform™ Reversed Glenoid Cannulated Glenospheres
Common Name (s):	Reverse Shoulder Prosthesis
Regulatory Class:	II
Regulation:	21 CFR 888.3660, Shoulder joint metal/polymer semi-constrained cemented prosthesis.
Product Codes:	PHX, KWS

Predicate Device Information

Predicate:	Aequalis PerFORM™ Reversed, Aequalis PerFORM+ Reversed Glenoid
510(k) Number:	K161742
Reference Device:	Aequalis Ascend Flex Shoulder System, Aequalis Reversed Shoulder Prosthesis
510(k) Number:	K151293

Device Description

The Tornier Perform™ Reversed Glenoid Cannulated Glenospheres are part of a reverse shoulder prosthesis consisting of cannulated cobalt chromium and titanium alloy glenospheres. The Tornier Perform Reversed Glenoid Cannulated Glenospheres are intended for replacement of the shoulder joint to reduce pain and improve shoulder mobility in comparison with preoperative status.

The Tornier Perform Reversed Glenoid Cannulated Glenospheres must be used in association with a compatible Tornier reversed glenoid and humeral component. The cannulated glenosphere can be used as part of the glenoid implant. The glenoid implant is composed of a baseplate with central and peripheral anchoring screws and a glenosphere. An optional press-fit post is available that can be used in lieu of the central anchoring screw.

Ancillary instruments are also provided for the implantation of the prosthesis.

Indications for Use

The Tornier Perform Reversed Glenoid Cannulated Glenospheres are indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle and with massive and non-repairable rotator cuff-tear with pain disabled by:

- Rheumatoid arthritis
- Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
- Correction of functional deformity
- Fractures of the humeral head
- Traumatic arthritis
- Revision of the devices if sufficient bone stock remains

Notes:

- All components are single use.
- The glenoid sphere implant is anchored to the bone with screws and is for non-cemented fixation.

Comparison of Technological Characteristics with the Predicate Device

New cannulated cobalt chromium and titanium glenospheres will be offered with the same intended use as the predicate system. The new glenospheres will be compatible with all existing components of the predicate Perform Reversed Glenoid Shoulder System. The design differences do not raise new issues of safety or effectiveness and are supported by performance testing and process validations.

Non-clinical Performance Testing

Non-clinical bench testing and process validations were performed to demonstrate substantial equivalence to the predicate device.

- Mechanical Bench Testing
    - Glenosphere Loosening
    - Taper Disassembly
    - Glenosphere Fatigue
- Simulated Use

Biocompatibility, packaging, cleaning and sterilization for the Tornier Perform™ Reversed Glenoid Cannulated Glenospheres were also assessed in accordance with recognized consensus standards.

Clinical Testing

No clinical studies were performed.

Conclusions

The Tornier Perform™ Reversed Glenoid Cannulated Glenospheres do not raise new questions of safety or effectiveness. Differences in technological characteristics have been addressed with performance testing. The results of performance testing for the added Tornier Perform™ Reversed Glenoid Cannulated Glenosphere cobalt chromium and titanium alloy components support substantial equivalence to the current Aequalis PerFORM™ Reversed, Aequalis PerFORM+ Reversed Glenoid (K161742).