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

November 12, 2021

Re: K211359
Trade/Device Name: Tornier Perform™ Patient-Matched Primary Reversed Glenoid and BLUEPRINT™ Patient Specific Instrumentation
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, QHE
Dated: October 8, 2021
Received: October 12, 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,

For Jiping Chen, PhD
Acting Division 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)*
K211359

Device Name
Tornier Perform™ Patient-Matched Primary Reversed Glenoid and
BLUEPRINT™ Patient Specific Instrumentation

Indications for Use *(Describe)*
Tornier Perform™ Patient-Matched Primary Reversed Glenoid

The Tornier Perform™ Patient-Matched Primary Reversed Glenoid implant is 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 glenohumeral joint if sufficient native glenoid bone remains

All components are single use.
The Patient-Matched Glenoid implant is anchored to the bone with screws and is for non-cemented fixation.
Note: A CT Scan is used to create the Tornier Perform Patient-Matched Primary Reversed Glenoid implant.

BLUEPRINT™ Patient Specific Instrumentation

BLUEPRINT ™ Glenoid Guides
The BLUEPRINT™ Glenoid Guides are intended to be used as surgical instruments to assist in the intraoperative positioning of glenoid components used with total anatomic or reversed shoulder arthroplasty procedures using anatomic landmarks that are identifiable on patient-specific preoperative CT scans.

BLUEPRINT™ 3D Planning Software
BLUEPRINT™ 3D Planning Software is a medical device for surgeons.
BLUEPRINT™ 3D Planning Software is intended to be used as a pre-surgical planner for shoulder replacement surgery.
BLUEPRINT™ 3D Planning Software requires CT scan images showing the anatomical shoulder structure in a DICOM format.
BLUEPRINT™ 3D Planning Software allows surgeons to visualize, measure, reconstruct, and annotate anatomic data.
BLUEPRINT™ 3D Planning Software allows surgeons to design patient specific components (Patient-Specific instruments and Tornier Perform™ Patient-Matched Primary Reversed Glenoid*) based on the pre-surgical plan.
BLUEPRINT™ 3D Planning Software leads to the generation of a planning report.
BLUEPRINT™ 3D Planning Software is to be used for adult men and women patients only whose bone maturity is reached and should not be used for diagnostic purpose.

Note: Measures and patient specific guide design are provided depending on the case profiles.
*Only if Patient-Specific instruments or Tornier Perform™ Patient-Matched Primary Reversed Glenoid are available in your geography.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Date Prepared: October 8, 2021

Administrative Information

Tornier Perform Patient-Matched Primary Reversed Glenoid (Implant)

Name:	Tornier, Inc.
Address:	10801 Nesbitt Avenue South Bloomington, MN 55437 United States of America

BLUEPRINT Patient Specific Instrumentation

Name:	Tornier SAS
Address:	161 rue Lavoisier 38330 Montbonnot Saint Martin-France
Contact Person:	Lisa Stahl
Title:	Principal Specialist, Regulatory Affairs
Phone (mobile):	612-849-9970
Fax:	952-426-7601

Device Information

Tornier, Inc.

Name of Device:	Tornier Perform™ Patient-Matched Primary Reversed Glenoid
Common Name (s):	Shoulder Prosthesis
Regulatory Class:	II
Regulation:	21 CFR 888.3660
Product Codes:	PHX, KWS

Tornier SAS

Name of Device:	BLUEPRINT™ Patient Specific Instrumentation
Common Name (s):	Patient Specific Instrumentation + 3D Planning Software
Regulatory Class:	II
Regulation:	21 CFR 888.3660
Product Codes:	KWS, QHE

Predicate Device Information

Tornier, Inc.

Primary Predicate:	AEQUALIS™ PERFORM Reversed Glenoid, K161742
Reference Device:	ZIMMER BIOMET Comprehensive Vault Reconstruction System, K152754 Exactech Equinoxe, K110708

Tornier SAS

Primary Predicate:	BLUEPRINT™ Patient Specific Instrumentation, K203315

Device Description

Tornier Perform™ Patient-Matched Primary Reversed Glenoid

The Tornier Perform™ Patient-Matched Primary Reversed Glenoid implant (Patient-Matched Glenoid) is intended to replace the native glenoid surface of the scapulohumeral joint as part of a reverse shoulder prosthesis.

The glenoid implant is composed of a baseplate with a press-fit post, peripheral anchoring screws, and a glenosphere. Ancillary instruments are also provided for the implantation of the prosthesis.

BLUEPRINT™ Patient Specific Instrumentation

BLUEPRINT™ Patient Specific Instrumentation is composed of two components: BLUEPRINT™ Glenoid Guides (hardware) and BLUEPRINT™ 3D Planning Software (software).

BLUEPRINT™ Patient Specific Instrumentation which includes the BLUEPRINT™ Glenoid Guides and BLUEPRINT™ 3D Planning Software is the responsibility of Tornier. Tornier is the legal manufacturer for the hardware and the software.

BLUEPRINT ™ Glenoid Guides

The BLUEPRINT ™ Glenoid Guides are patient-specific instruments specially designed to facilitate the implantation of WRIGHT-TORNIER glenoid prostheses.

The BLUEPRINT™ Glenoid Guides are designed and manufactured based on a pre-operative plan generated only by the software BLUEPRINT™ 3D Planning Software.

BLUEPRINT™ 3D Planning Software

BLUEPRINT™ 3D Planning Software is a software connected to an Online Management System (OMS). The user interface software is installed on a computer is intended to be used by orthopedic surgeons, as a preoperative planning software for shoulder arthroplasty surgery (anatomic and reversed).

It is intended to help to plan an operation by allowing surgeons to:

- Plan for shoulder arthroplasty cases
- Position and select glenoid and humeral implants,
- Simulate the prosthetic range of motion,
- Interact with implants and different computed measurements
- Generate information required to design a patient-specific glenoid component when appropriate.

TORNIER

Intended Use

Tornier Perform™ Patient-Matched Primary Reversed Glenoid
The implant is intended for replacement of the shoulder joint to reduce pain and improve shoulder mobility in comparison with preoperative status.

BLUEPRINT™ Patient Specific Instrumentation

BLUEPRINT ™ Glenoid Guides

The BLUEPRINT™ Glenoid Guides are intended to be used as surgical instruments to assist in the intraoperative positioning of glenoid components used with total anatomic or reversed shoulder arthroplasty procedures using anatomic landmarks that are identifiable on patient-specific preoperative CT scans.

BLUEPRINT™ 3D Planning Software

BLUEPRINT™ 3D Planning Software is an application that helps a surgeon plan their patients' shoulder prosthesis surgery. When possible, it generates the information required to produce patient specific components.

Indications for Use

Tornier Perform™ Patient-Matched Primary Reversed Glenoid

The Tornier Perform™ Patient-Matched Primary Reversed Glenoid implant is 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:

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All components are single use.

The Patient-Matched Glenoid implant is anchored to the bone with screws and is for non-cemented fixation.

Note: A CT Scan is used to create the Tornier Perform Patient-Matched Primary Reversed Glenoid implant.

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Comparison to Predicate Device

Tornier Perform™ Patient-Matched Primary Reversed Glenoid

The TORNIER PERFORM™ Patient-Matched Primary Reversed Glenoid and the predicate AEQUALIS™ PERFORM Reversed Glenoid have the same intended use, same principle of operation, and similar technological features. The subject device provides patient-specific augmentation.

BLUEPRINT™ Patient Specific Instrumentation

The subject device BLUEPRINT™ Patient Specific Instrumentation and the predicate device BLUEPRINT™ Patient Specific Instrumentation (K203315) have the same intended use, similar principal of operation and similar general technological features.

Differences for subject BLUEPRINT™ Patient Specific Instrumentation include:

- For the hardware: New guides dedicated to Tornier Perform™ Patient-Matched Primary Reversed Glenoid with nonfunctional dimensions changes, delivered sterile.
- For the software, planning for Tornier Perform™ Patient-Matched Primary Reversed Glenoid additional measurement and screw planning.

Non-clinical Performance Testing

Tornier Perform™ Patient-Matched Primary Reversed Glenoid
Non-clinical testing was performed to demonstrate substantial equivalence to the predicate device.

- Baseplate Pullout
- Fatigue
- Reverse Glenoid Loosening
- Range of Motion
- MRI compatibility evaluation
- Porous Structure

Biocompatibility, sterilization, cleaning, endotoxin, particulate, packaging, shelf life, and distribution for the Tornier Perform™ Patient-Matched Primary Reversed Glenoid components were also assessed in accordance with recognized consensus standards.

BLUEPRINT™ Patient Specific Instrumentation
Technological differences between the subject and predicate hardware devices are supported by the dimensional test performed on the predicate device hardware which remain applicable to the subject hardware device, as the changes to the subject device do not impact functional dimensions or material, and cadaveric test performed on the subject device.

Technological differences between the subject and predicate software devices are supported with verification and validation evaluations. The operating principle of the subject device is the same as that of the predicate device.

The differences in design specifications do not raise new questions of safety and effectiveness over the predicate device as demonstrated in validation testing.

Clinical Testing

No clinical studies were performed.

Conclusions

Tornier Perform™ Patient-Matched Primary Reversed Glenoid

The Tornier Perform™ Patient-Matched Primary Reversed Glenoid does 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 Tornier Perform™ Patient-Matched Primary Reversed Glenoid support substantial equivalence to the primary predicate AEQUALIS™ PERFORM™ Reversed Glenoid (K161742, cleared November 15, 2016).

BLUEPRINT™ Patient Specific Instrumentation

The BLUEPRINT™ Patient Specific Instrumentation does not raise new questions of safety or effectiveness. Differences in technological characteristics have been addressed with verification and validation testing. The results support substantial equivalence to the predicate BLUEPRINT™ Patient Specific Instrumentation (K203315, cleared April 15, 2021).