Tornier SAS
Aymen Azaiez
Principal Regulatory Affairs Specialist
161 Rue Lavoisier
Montbonnot Saint Martin, 38330
France

February 21, 2024

Re: K232265
Trade/Device Name: 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: January 22, 2024
Received: January 23, 2024

Dear Aymen Azaiez:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2024.02.21 14:12:55 -05'00'

for: Farzana Sharmin, PhD
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)*
K232265

Device Name
BLUEPRINT™ Patient Specific Instrumentation

Indications for Use *(Describe)*

Hardware

The BLUEPRINT™ Glenoid Guides are patient-specific drill guides. They have been specially designed 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.

Software

Blueprint® is a medical device for surgeons.
Blueprint® is intended to be used as a pre-surgical planner for shoulder replacement surgery.
Blueprint® requires CT scan images showing the anatomical shoulder structure in a DICOM format.
Blueprint® allows surgeons to visualize, measure, reconstruct, and annotate anatomic data.
Blueprint® 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® leads to the generation of a planning report.
Blueprint® 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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Summary of Safety and Effectiveness information
Traditional 510(k) Premarket – BLUEPRINT™ Patient Specific Instrumentation

Date Prepared: February 21, 2024

Device name

Trade name: BLUEPRINT™ Patient Specific Instrumentation
Common name: Patient Specific Instrumentation + Blueprint®
Classification name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulation number: (§888.3660)

Submitter

Name: TORNIER SAS
Address 161 rue Lavoisier
38330 Montbonnot Saint Martin- France
Registration Number: 3000931034

Company contact

Company Name: TORNIER SAS
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Classification

Device class: Class II
Classification panel: Orthopedic
Product code: PHX, KWS, QHE

Equivalent / Predicate device

Trade name	510(k) Number	Decision date	Applicant
BLUEPRINT™ Patient Specific Instrumentation (PRIMARY)	**K211359**	**November 12, 2021**	**TORNIER SAS**
BLUEPRINT™ Patient Specific Instrumentation (Additional)	K203315	April 15, 2021	TORNIER SAS

TORNIER

Device description

BLUEPRINT™ Patient Specific Instrumentation is composed of two components: BLUEPRINT™ Glenoid Guides (hardware) and Blueprint® (software).

BLUEPRINT™ Patient Specific Instrumentation which includes the BLUEPRINT™ Glenoid Guides and Blueprint® is the responsibility of Tornier. Tornier SAS is the legal manufacturer for the hardware and the software.

Hardware

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

The BLUEPRINT™ Glenoid Guides are designed and manufactured based on a pre-operative plan generated only by the software Blueprint®.

Software

Blueprint® 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 components when appropriate.

Compatible Implants

The software can be used with the following the commercially available Stryker implants:

- Aequalis PerFORM Shoulder System (K111902),
- Aequalis PerFORM+ Shoulder System (K160975 / K150583),
- Aequalis Reversed Shoulder Prothesis (K151293 / K140478 / K132285 / K100142 / K081059 / K061439 / K050316 / K030941),
- Aequalis Ascend Flex Shoulder System (K151293 / K140082 / K122698),
- Simpliciti Shoulder System (K143552).

- Aequalis™ PerFORM™ Reversed Glenoid and Aequalis™ PerFORM™+ Reversed Glenoid (K183696)
- Perform® Humeral System – Stem (K201315)
- Aequalis™ Flex Revive Shoulder System (K191318)
- TORNIER PERFORM™ Patient-Matched Primary Reversed (K211359)
- Tornier Perform® Humeral System – Stemless (K220418)
- ReUnion Reversible Fracture System (RFX), ReUnion Reverse Shoulder Arthroplasty System (RSA), ReUnion Total Shoulder Arthroplasty System (TSA) (K202289)

Materials

The commercially available BLUEPRINT™ Glenoid Guides are manufactured from titanium (Ti6Al4V) according to ISO 5832-3.

Intended Use

Hardware

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.

Software

Blueprint® 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

Hardware

The BLUEPRINT™ Glenoid Guides are patient-specific drill guides. They have been specially designed 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.

Software

Blueprint® is a medical device for surgeons.

Blueprint® is intended to be used as a pre-surgical planner for shoulder replacement surgery.

Blueprint® requires CT scan images showing the anatomical shoulder structure in a DICOM format.

Blueprint® allows surgeons to visualize, measure, reconstruct, and annotate anatomic data.

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Blueprint® leads to the generation of a planning report.

Blueprint® 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.

Comparison to Predicate Device

The subject device BLUEPRINT™ Patient Specific Instrumentation and the predicate device BLUEPRINT™ Patient Specific Instrumentation (K211359) have the same intended use, similar principal of operation and similar general technological features.

The subject device hardware is identical to the predicate device hardware.

Differences for subject device software include:

- Initial Auto-segmentation module for revision cases containing metallic prosthesis.
- User planning preferences settings

Performance data

Technological differences between the subject and predicate software devices are supported by software verification and validation activities. These activities include functional tests, validation and compatibility for new implant integration, as well as the validation and reproducibility of anatomical measures, planning measures, planning features, and segmentation. The operating principle of the subject device is the same as that of the predicate device.

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

Substantial equivalence conclusion

The subject device, the BLUEPRINT™ Patient Specific Instrumentation, does not raise new questions of safety or effectiveness. Differences in technological characteristics have been addressed by software verification and validation activities. The results support substantial equivalence to the predicate BLUEPRINT™ Patient Specific Instrumentation (K211359, cleared November 12, 2021).