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

April 15, 2021

Re: K203315
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: KWS
Dated: March 16, 2021
Received: March 17, 2021

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 (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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2021.04.15 11:41:32 -04'00'

For Vesa Vuniqi
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203315

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™ 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 orthopedic 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 guides 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 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.

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.

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Traditional 510(k) Premarket – BLUEPRINT™ Patient Specific Instrumentation

Device name

Trade name: BLUEPRINT™ Patient Specific Instrumentation
Common name: Patient Specific Instrumentation + 3D Planning Software
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: KWS

Equivalent / Predicate device

Trade name	510(k) Number	Decision date	Applicant
BLUEPRINT™ Patient Specific Instrumentation (PRIMARY)	**K162800**	**June 10, 2016**	**TORNIER SAS**
PROPHECY INVISION Pre-operative Navigation System (Reference)	K170968	August 16, 2017	Wright Medical Technology, Inc.

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Device description

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.

Hardware

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.

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
- Design a patient specific guide for the glenoid component when appropriate.

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.

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Software

The **BLUEPRINT™ 3D Planning Software** is intended to be used as a medical software to assist in pre-operative surgical planning for shoulder surgery.

Indications For Use

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™ 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 orthopedic 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 guides 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 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.

Comparison to Predicate Device

The subject device BLUEPRINT™ Patient Specific Instrumentation and the predicate device BLUEPRINT™ Patient Specific Instrumentation (K162800) have the same intended use, similar principal of operation and similar general technological features.

The subject device has similar manual segmentation as the reference device PROPHECY INVISION Pre-operative Navigation System.

Differences for subject BLUEPRINT™ Patient Specific Instrumentation include:

- For the hardware: nonfunctional dimensions, addition of a new guide reference similar to the predicate device, and packaging/label changes for clarity

- For the software, additional measurements, interaction with an application for automatic processing and an application for manual processing, and additional compatible Wright-Tornier implants.

Performance data

Technological differences between the subject and predicate hardware devices are supported by the dimensional and cadaveric tests performed on the predicate device hardware (K162800) which remain applicable to the subject hardware device as the changes to the subject device do not impact functional dimensions or material.

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.

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 with verification and validation testing. The results support substantial equivalence to the predicate BLUEPRINT™ Patient Specific Instrumentation (K162800, cleared June 10, 2016).