DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 27, 2016

Tornier Sas
Aymen Azaiez
Regulatory Affairs Specialist
161 rue Lavoisier
38330 Montbonnot Saint-Martin, France

Re: K161789
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: November 24, 2016
Received: November 28, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Caroline Rhim -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K161789

Device Name
BLUEPRINT™ Patient Specific Instrumentation

Indications for Use *(Describe)*

The hardware

The Aequalis 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 shoulder arthroplasty procedures using anatomic landmarks that are identifiable on patient-specific preoperative CT-scans.

Aequalis PerFORM Anatomic Glenoid Guide is used by surgeons to facilitate the placement of the Aequalis PerFORM glenoids and the Aequalis PerFORM + glenoids.

The software

The BLUEPRINT 3D planning software is a medical device for surgeon composed of one software component. It is intended to be used as a pre-surgical planner for shoulder orthopedic surgery.

BLUEPRINT 3D planning software runs on standard personal and business computers running Microsoft Windows or Mac OS operating systems.

The software supports DICOM standard to import the CT-Scan (Computed Tomography) images of the patient. Only CT-Scan modality can be loaded with BLUEPRINT3D planning software.

BLUEPRINT 3D planning software allows surgeon to visualize, measure, reconstruct, and annotate anatomic data. It allows surgeon to design patient specific guides based on the presurgical plan.

This device is intended for use provided anatomic reference points necessary for positioning of the guide are present on the CT scan.

The software leads to the generation of a surgery report along with a 3D file of the patient-specific guide.

BLUEPRINT 3D planning software does not include any system to manufacture the guide.

BLUEPRINT 3D planning software is to be used for adult patients only and should not be used for Diagnostic purpose.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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Summary of Safety and Effectiveness information
Special 510(k) Premarket – BLUEPRINT™ Patient Specific Instrumentation

1) Device name

Trade name: BLUEPRINT™ Patient Specific Instrumentation

Common name: Patient specific instrumentation + 3D planning software

Classification name: Prosthesis, Shoulder, Semi-constrained, Metal/Polymer Cemented (§888.3660)

2) Submitter :

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

3) Company contact :

Tornier SAS
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4) Classification

Device class: Class II
Classification panel: Orthopedic
Product code: KWS

5) Equivalent / Predicate device :

Primary: BLUEPRINT™ Patient Specific Instrumentation, Tornier SAS (K143374)
Primary: BLUEPRINT™ Patient Specific Instrumentation, Tornier SAS (K160555)
Reference: Aequalis PerFORM+ Shoulder System (K150583)
Reference: Aequalis PerFORM+ Shoulder System (K160975)

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6) Device description :

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

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

The hardware

The *Aequalis Glenoid Guides* are patient-specific instruments specially designed to facilitate the implantation of the Aequalis PerFORM shoulder prostheses and the Aequalis PerFORM + shoulder prostheses.

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

The software

BluePrint 3D Planning software is composed of one software component connected to an Online Management System (OMS). The software installed on a computer is intended to be used by orthopedic surgeons, as a preoperative planning software for shoulder arthroplasty surgery (= total anatomic shoulder replacement).

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

- position and select the glenoid implant,
- design a patient specific pin guide.

This submission seeks clearance for:

- **Hardware: adding Aequalis PerFORM + glenoids (K150583 and K160975) to the indications for use of the Titanium and Polyamide Aequalis PerFORM Anatomic Glenoid Guides (respectively K160555 and K143374)**
- **Software:**
  - **Adding Aequalis™ PerFORM + prosthesis (K150583 and K160975) into the pre-operative surgical planning part.**
  - **Updating of the contraindications**

These modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device.

Intended Use

The hardware

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

The 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.

7) Materials :

There is no change regarding the material of the subject Aequalis Perform Anatomic Glenoid Guides. The commercially available *Aequalis Glenoid Guides* are manufactured from medical grade polyamide 2200 or Titanium.

8) Indications :

The hardware

The *Aequalis 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 shoulder arthroplasty procedures using anatomic landmarks that are identifiable on patient-specific preoperative CT-scans.

Aequalis PerFORM Anatomic Glenoid Guide is used by surgeons to facilitate the placement of the Aequalis PerFORM and Aequalis PerFORM + glenoids.

The software

The *BLUEPRINT 3D planning software* is a medical device for surgeon composed of one software component. It is intended to be used as a pre-surgical planner for shoulder orthopedic surgery.

BLUEPRINT 3D planning software runs on standard personal and business computers running Microsoft Windows or Mac OS operating systems.

The software supports DICOM standard to import the CT-Scan (Computed Tomography) images of the patient. Only CT-Scan modality can be loaded with *BLUEPRINT 3D planning software.*

BLUEPRINT 3D planning software allows surgeon to visualize, measure, reconstruct, and annotate anatomic data. It allows surgeon to design patient specific guides based on the presurgical plan.

This device is intended for use provided anatomic reference points necessary for positioning of the guide are present on the CT scan.

The software leads to the generation of a surgery report along with a 3D file of the patient-specific guide.

BLUEPRINT 3D planning software does not include any system to manufacture the guide.

BLUEPRINT 3D planning software is to be used for adult patients only and should not be used for diagnostic purpose.

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9) Summary of technological characteristics

Table 1 Main features comparison

Main features or system characteristics	***BLUEPRINT™ Patient Specific Instrumentation SUBJECT DEVICE SYSTEM***	***BLUEPRINT™ Patient Specific Instrumentation (K143374) PRIMARY***	***BLUEPRINT™ Patient Specific Instrumentation (K160555) PRIMARY***	**Aequalis PerFORM+ Shoulder System (K150583)** ***Reference***	**Aequalis PerFORM+ Shoulder System (K160975)** ***Reference***
Material	Ti6AI4V Polyamide 2200	Polyamide 2200	Ti6AI4V	UHMWPE CoCr	UHMWPE CoCr
Standard	ISO 5832-3 USP Class VI compatible	USP Class VI compatible	ISO 5832-3	ISO 5834-2, ISO 5832-7	ISO 5834-2, ISO 5832-7
Manufacturing	3D printing	3D printing	3D printing	Traditional machining	Traditional machining
Product Code	KWS	KWS	KWS	KWS	KWS
Surgical procedure	Total anatomic shoulder arthroplasty	Total anatomic shoulder arthroplasty	Total anatomic shoulder arthroplasty	Total anatomic shoulder arthroplasty	Total anatomic shoulder arthroplasty
Single-use	Yes	Yes	Yes	Yes	Yes
Sterile	No	No	No	Yes	Yes
Manufacturer	Tornier SAS	Tornier SAS	Tornier SAS	Tornier, Inc.	Tornier, Inc.
Software	Assist surgeon in pre-operative surgical planning	Assist surgeon in pre-operative surgical planning	Assist surgeon in pre-operative surgical planning	NA	NA

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate devices.

10) Performance data

BLUEPRINT™ Patient Specific Instrumentation was validated through rationalized equivalences (technical, clinical and biological) proving the compatibility of BLUEPRINT™ Patient Specific Instrumentation with both Aequalis™ PerFORM and Aequalis™ PerFORM+ implants and to assess that no new safety or effectiveness questions were raised with this device.

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Table 2: Performance Data

Validation &/or Verification Method	Acceptance Value /Criteria	Results
Verify that the patient-specific solution is compatible with the instrumentation of Aequalis™ PerFORM+ in terms of technical, biological and clinical equivalences	Proven technical, biological and clinical equivalences	Acceptable
Compare post-operative clinical data with pre-operative plans to verify the accuracy of the patient-specific solution in Aequalis™ PerFORM+ configuration	Correct positioning of the main pin	Acceptable
Perform tests of software features when the Aequalis™ PerFORM+ is selected	No dysfunction of the software features and the Aequalis™ PerFORM+ is correctly displayed	Acceptable

11) Substantial equivalence conclusion

Based upon this comparative study, substantial equivalence of *BLUEPRINT™ Patient Specific Instrumentation* to the predicates can be demonstrated on the following grounds, according to the FDA's Guidelines for Substantial Equivalence Decision making Process:

- *BLUEPRINT™ Patient Specific Instrumentation (pending device)* is compared to the predicate devices and the reference devices.
- *BLUEPRINT™ Patient Specific Instrumentation (pending device)* has the sufficiently equivalent intended use as the predicate devices: *BLUEPRINT™ Patient Specific Instrumentation (K143374) and BLUEPRINT™ Patient Specific Instrumentation (K160555),*
- *BLUEPRINT 3D planning software* (pending device) is equivalent to the *BLUEPRINT 3D planning software (K143374) and BLUEPRINT™ Patient Specific Instrumentation (K160555)*.
- *BLUEPRINT 3D planning software* (pending device) user manual is similar in indications precautions, warnings, and instructions as the predicate device: *(K143374) and (K160555)*.
- Major technological characteristics are equivalent between *BLUEPRINT™ Patient Specific Instrumentation (pending device)* and the predicate devices:
  - Equivalence of general features
  - Equivalent surgical procedures
  - Equivalent intended use, indications for use
  - Equivalent material

Therefore, in the light of the above information, the *BLUEPRINT™ Patient Specific Instrumentation* is considered equivalent to the predicate devices and no safety and effectiveness issues were raised with this device.