DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 22, 2017

TORNIER SAS
Aymen Azaiez
Regulatory Affairs Specialist
161 rue Lavoisier
38330 Montbonnot Saint Martin
France

Re: K162800
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: September 30, 2016
Received: October 5, 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,

Mark N. Melkerson -S

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 below.

510(k) Number *(if known)*

K162800

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 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, annotate and edit anatomic data. It allows surgeon to design glenoid patient-specific guides based on the pre-surgical plan.

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

BLUEPRINT™ 3D Planning Software does not include any system to manufacture the glenoid patient-specific 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

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) Primary Predicate Device and Reference devices

Trade name	510(k) Number	Decision date	Applicant
BLUEPRINT™ Patient Specific Instrumentation (PRIMARY)	**K160555**	**10th June 2016**	**TORNIER SAS**
Materialise Glenoid Positioning System (Reference)	K153602	26th April 2016	MATERIALISE NV
TraumaCad Mobile Release 2.0 (Reference)	K160001	12th February 2016	VOYANT HEALTH LTD
DYONICS PLAN HIP IMPINGEMENT PLANNING SYSTEM (Reference)	K132636	17th October 2016	SMITH & NEPHEW, INC
OSIRIX MD (Reference)	K101342	20th August 2010	PIXMEO SARL

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6) Device description

BLUEPRINT™ Patient Specific Instrumentation is composed of two components: *BLUEPRINT™ Glenoid Guides* (hardware) and *BLUEPRINT™ 3D Planning Software* (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 by the *BLUEPRINT™ 3D Planning Software.*
All *BLUEPRINT™ Glenoid Guides* are patient-specific, single use and delivered non-sterile.

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 (anatomic and reversed).

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

- Position and select glenoid implant,
- Position and select humeral implant,
- Display bone density and reaming surface,
- Simulate the prosthetic range of motion,
- Design a patient specific guide for the glenoid component.

7) Materials

The commercially available *BLUEPRINT™ Glenoid Guides* are manufactured from medical grade polyamide (PA 2200) or titanium (Ti6Al4V).

8) 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

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

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9) 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

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BLUEPRINT™ 3D Planning Software does not include any system to manufacture the glenoid patient-specific guide.

BLUEPRINT™ 3D Planning Software is to be used for adult patients only and should not be used for diagnostic purpose.

10) Summary of technological characteristics

BLUEPRINT™ Patient Specific Instrumentation (Subject Device System) has an equivalent intended use and the same fundamental scientific technology as the primary predicate and reference devices. The subject device is intended for total shoulder arthroplasty, (same as the predicate device) and for reverse shoulder arthroplasty (same as the reference device Materialise Glenoid Positioning System (K153602)). The subject device is equivalent to the predicate device for the main technological characteristics. Additionally, the subject device is equivalent to reference devices:

- Voyant Health, Ltd. TRAUMACAD VERSION 2.0 (K160001) for the humeral planning functionality
- The Smith & Nephew DYONICS PLAN Hip Impingement Planning System (K132636) for the range of motion functionality
- PIXMEO SARL OsiriX MD (K101342) for the bone density functionality

The design differences have been demonstrated to not affect safety or effectiveness or raise new issues of safety or effectiveness.

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11) Performance data

BLUEPRINT™ Patient Specific Instrumentation (Subject Device System) was validated through non-clinical testing for the *BLUEPRINT 3D Planning Software*.
The validation of ***BLUEPRINT™ Patient Specific Instrumentation*** (Subject Device System) was already proven via BLUEPRINT™ Patient Specific Instrumentation (K143374) and BLUEPRINT™ Patient Specific Instrumentation (K160555), including polyamide and titanium materials, when used for helping the positioning of the Aequalis PerFORM (K111902) implant. The performed testing for validation of the design, manufacturing, biocompatibility, sterility, dimensions and the accuracy of the guide are applicable to the subject device. Technical, clinical and biological equivalences have been demonstrated in order to use *BLUEPRINT™ Glenoid Guides* with additional WRIGHT-TORNIER implants such as Aequalis PerFORM+ (K160975) and Aequalis Reversed II (K151293).

All *BLUEPRINT™ Glenoid Guides* aim to drill a K-wire guiding the main reaming, regardless of the implant planned. All *BLUEPRINT™ Glenoid Guides* have exactly the same design, except *BLUEPRINT™ Glenoid Guides* in titanium dedicated to be used with Aequalis PerFORM (K111902) and Aequalis PerFORM+ (K160975) implants which include an orientation hole for controlling rotation of the implant (cleared via BLUEPRINT™ Patient Specific Instrumentation (K160555)).

12) Conclusion

BLUEPRINT™ Patient Specific Instrumentation (Subject Device System) described in this section has an equivalent intended use and the same fundamental scientific technology as the cleared BLUEPRINT™ Patient Specific Instrumentation (K160555) and the reference devices.
Based on the performance data presented for the design differences between the subject and predicate device, Tornier concludes that subject device is substantially equivalent to the predicate device.

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