October 10, 2024

Stryker Corporation (Tornier, S.A.S.)
Aymen Azaiez
Principal Regulatory Affairs Specialist
161 rue Lavoisier
Montbonnot-Saint-Martin, 38330
France

Re: K241491
Trade/Device Name: Blueprint Patient-Specific Instrumentation; Shoulder iD Primary Reversed Glenoid
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: September 6, 2024
Received: September 6, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Farzana Sharmin -S
Digitally signed by Farzana Sharmin -S
Date: 2024.10.10 12:23:24 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241491

Device Name

Blueprint Patient-Specific Instrumentation;
Shoulder iD Primary Reversed Glenoid

Indications for Use *(Describe)*

BLUEPRINT™ Patient Specific Instrumentation IFU:
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 Shoulder iD™ 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 Shoulder iD™ Primary Reversed Glenoid are available in your geography.

Shoulder iD™ Primary Reversed Glenoid IFU:
The Shoulder iD™ 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 Shoulder iD™ Primary Reversed Glenoid implant is anchored to the bone with screws and is for non-cemented fixation.
Note: A CT Scan is used to create the Shoulder iD™ Primary Reversed Glenoid implant

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K241491

510(k) Summary

Prepared on: 2024-09-09

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Stryker Corporation (Tornier, S.A.S.)
Applicant Address	161 rue Lavoisier Montbonnot-Saint-Martin 38330 France
Applicant Contact Telephone	+33648381036
Applicant Contact	Mr. Aymen Azaiez
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Correspondent Contact Telephone	+33648381036
Correspondent Contact	Mr. Aymen Azaiez
Correspondent Contact Email	aymen.azaiez@stryker.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Blueprint Patient-Specific Instrumentation; Shoulder iD Primary Reversed Glenoid
Common Name	Shoulder Prosthesis, Reverse Configuration
Classification Name	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulation Number	888.3660
Product Code(s)	PHX, KWS, QHE

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K232265	BLUEPRINT™ Patient Specific Instrumentation	PHX
K211359	BLUEPRINT™ Patient Specific Instrumentation + Tornier Perform	PHX
K222987 (Reference)	Akunah REFLECT	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

BLUEPRINT™ Patient Specific Instrumentation
Blueprint Patient Specific Instrumentation is composed of two components: Blueprint Glenoid Guides (hardware) and Blueprint Planning Software (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 Planning Software.
Blueprint™ Planning Software
Blueprint Planning Software is a software connected to an Online Management System (OMS). The user interface software is installed on a computer and 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.

Shoulder iD™ Primary Reversed Glenoid
The Shoulder iD Primary Reversed Glenoid implant (Shoulder iD) 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

BLUEPRINT™ Patient Specific Instrumentation IFU:
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Blueprint® is intended to be used as a pre-surgical planner for shoulder replacement surgery.
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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 Shoulder iD™ Primary Reversed Glenoid are available in your geography.

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The Shoulder iD™ 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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• 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 Shoulder iD™ Primary Reversed Glenoid implant is anchored to the bone with screws and is for non-cemented fixation.
Note: A CT Scan is used to create the Shoulder iD™ Primary Reversed Glenoid implant

Indications for Use Comparison

21 CFR 807.92(a)(5)

For BLUEPRINT Patient Specific Instrumentation, the indications for use of the subject device are identical to the predicate device.
For Shoulder iD Primary Reversed Glenoid, the indications for use of the subject device (Shoulder iD Primary Reversed Glenoid) and of the predicate device (Tornier Perform Patient-Matched Primary Reversed Glenoid) are identical except for the name of the device.

Technological Comparison 21 CFR 807.92(a)(6)

BLUEPRINT Patient Specific Instrumentation
The subject and predicate hardware devices have identical technological features.
Technological differences between the subject and predicate software devices do not raise any different questions of safety and effectiveness and they are addressed though performance testing.

Shoulder iD Primary Reversed Glenoid.
The Shoulder iD Primary Reversed Glenoid and the predicate Tornier Perform Patient-Matched Primary Reversed Glenoid have the same technological features. The only differences between the subject and predicate devices are the brand name and the updated Operative Technique for the subject device. The difference in the operative technique does not raise any different questions of safety and effectiveness and is addressed though performance testing.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

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.

Shoulder iD Primary Reversed Glenoid
Non-clinical Reverse Glenoid Loosening testing was conducted to confirm substantial equivalence to the predicate device in manual bone preparation conditions.

No clinical studies were performed.

BLUEPRINT™ Patient Specific Instrumentation:
The subject device hardware BLUEPRINT™ Patient Specific Instrumentation does not raise any different questions of safety and effectiveness over the predicate device. Technological differences between the subject and predicate hardware devices are supported by the dimensional and cadaveric tests performed on the predicate device hardware which are still applicable on the subject hardware device as the changes to the subject device do not impact functional dimensions nor material.

Shoulder iD Primary Reversed Glenoid
The Shoulder iD Primary Reversed Glenoid does not raise different questions of safety or effectiveness. There are no differences in technological characteristics between the predicate and subject devices. The results of the performance testing for the Shoulder iD Primary Reversed Glenoid support substantial equivalence to the predicate Tornier Perform Patient-Matched Primary Reversed Glenoid (K211359, cleared November 12, 2021).