April 3, 2026

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

Re: K253674
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: March 4, 2026
Received: March 4, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Joseph P. Russell -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253674

Please provide the device trade name(s).

Blueprint Patient-Specific Instrumentation

Please provide your Indications for Use below.

Blueprint is a medical device for surgeons.

Blueprint is intended to be used as a pre-surgical planner for shoulder replacement surgery or shoulder instability treatment of cases with anterior glenoid bone loss.

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 generates a planning report.

Blueprint arthroplasty planning is to be used for adult men and women patients only whose bone maturity is reached and should not be used for diagnostic purpose.

Blueprint instability planning is to be used for 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253674

510(k) Summary

Prepared on: 2026-04-03

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
Applicant Contact Email	aymen.azaiez@stryker.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Blueprint Patient-Specific Instrumentation
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
K241491	BLUEPRINT™ Patient Specific Instrumentation	PHX
K222987	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 Patient Specific Instrumentation which includes the Blueprint Glenoid Guides and Blueprint Planning Software is the responsibility of Tornier. Tornier is the legal manufacturer for the hardware and the software.

Blueprint™ Glenoid Guides
The Blueprint Glenoid Guides are patient-specific instruments specially designed to facilitate the implantation of Stryker 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 surgery (anatomic, reversed and instability procedure).
It is intended to help to plan an operation by allowing surgeons to:
• Plan for shoulder arthroplasty and instability cases
• Position and select glenoid and humeral implants for arthroplasty cases,
• 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Blueprint is a medical device for surgeons.

Blueprint is intended to be used as a pre-surgical planner for shoulder replacement surgery or shoulder instability treatment of cases with anterior glenoid bone loss.

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 generates a planning report.

Blueprint arthroplasty planning is to be used for adult men and women patients only whose bone maturity is reached and should not be used for diagnostic purpose.

Blueprint instability planning is to be used for 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The intended use and the indications for use of the subject device hardware are identical to the predicate device.
The intended use of the subject device software is the same as for the predicate device software which helps surgeons plan their patients' shoulder surgery. The indications for use of the subject device software has been updated to include shoulder instability treatment of cases with anterior glenoid bone loss.

Technological Comparison

21 CFR 807.92(a)(6)

The subject and predicate hardware devices have identical technological features. Main differences of technological characteristics consist of :
> Algorithm improvements for:
- Glenoid premorbid prediction for arthroplasty and instability
- Shoulder instability planning

> Arthroplasty auto-planning function expanded to include Reverse Shoulder Arthroplasty
> New algorithm related to Non-nominal case detection based on a deep learning model. The new detector algorithm is deployed in both Blueprint (local) and OMS (cloud).
> Compatibility to additional cleared devices
- Humeral System Fracture (K220914)
- Tornier HRS Line extension (K241878)

These 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.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The subject and predicate hardware devices are identical and the dimensional and cadaveric tests performed on the predicate device hardware are still applicable on the subject hardware device (No hardware change).

Technological differences between the subject and predicate software devices are supported by software verification and validation activities. These activities include functional testing, validation and compatibility testing for new implant integration, as well as validation and reproducibility assessments of anatomical measurements, planning measurements, planning features, and segmentation.

The operating principle of the subject device is the same as that of the predicate device.

>> Non-nominal case detection (AI/ML model)

The machine learning (ML) models integrated into Blueprint were trained, tuned/developed and externally validated in accordance with established internal procedures. Model performance was evaluated using a dedicated external validation dataset that was independent from the data used for model training and tuning/development. The training dataset, the development/tuning dataset, and the external validation dataset were defined as separate datasets from the outset of development to mitigate the risk of bias and prevent data leakage across datasets.

> Training, development/tuning dataset, and external validation data information

ML models were developed with datasets from 757 sites in a total of 6545 cases.
We trained the ML models with 90% of the dataset, developed/tuned with 10%.
The training and tuning/development data is constructed by combining 2975 regular Blueprint cases with 1605 CT scan of interest (for geographic diversity and increased clinical relevance) and other CT scan such as CT of the knee or hip (305 cases).
The total unique dataset employed for training and development/tuning is 4885 CT scans while external validation is performed with a unique dataset of size 1660 cases. This comprehensive dataset was designed to cover the intended use population while ensuring a variety of data, maintaining diverse patient characteristics.
The external validation dataset is based on 1000 regular Blueprint patient cases corresponding to 1660 CT scans series. To cover all type patients, age and sex the test dataset is composed of regular Blueprint cases.

> Subgroup definition (generalizability)

Datasets were divided according to the subgroups listed below:

- Demographics
- Patient Sex
- Patient Age
- Equipment and Protocols for Image Collection
- Institutions
- Manufacturer
- Manufacturer Model Name

> Reference Standard (Truthing Process)

The performance of the detection ML model was evaluated on the external validation dataset by comparison against a predefined reference standard (ground truth).
The results obtained using the external validation dataset met the predefined acceptance criteria for ML model performance, as defined in internal procedures. These results support the demonstration of substantial equivalence of the subject device to the identified predicate device.

> Independence of Training and External Validation Data

External validation datasets were collected independently from the training and development data to mitigate the risk of bias and support the reliability of the validation results.
A fully independent dataset was used for external validation to assess model performance across the overall intended population as well as each of the predefined sub-groups described previously.
The results of the external validation met the predefined acceptance criteria, indicating acceptable performance of the ML model for its intended use population and supporting its ability to generalize to previously unseen data representative of the intended clinical context.

No clinical studies were performed.

The subject device hardware BLUEPRINT™ Patient Specific Instrumentation is identical to the predicate device.
Non-clinical test results support substantial equivalence of the subject device, the BLUEPRINT Patient Specific Instrumentation, to the predicate BLUEPRINT Patient Specific Instrumentation (K241491), cleared October 10, 2024