June 12, 2026

Stryker Corporation (Tornier, Inc.)
Jang Long
Staff Specialist, Regulatory Affairs
10801 Nesbitt Ave. S.
Bloomington, Minnesota 55437

Re: K260102
Trade/Device Name: Tornier Perform Reversed Glenoid and Tornier Perform Reversed Augmented Glenoid Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: April 15, 2026
Received: April 15, 2026

Dear Jang Long:

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,

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.	K260102

Please provide the device trade name(s).

Tornier Perform Reversed Glenoid and Tornier Perform Reversed Augmented Glenoid Shoulder System

Please provide your Indications for Use below.

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 the devices if sufficient bone stock remains

Notes:
- All components are single use.
- The glenoid sphere implant is anchored to the bone with screws and is for non-cemented fixation.
- All compatible humeral components are available for cemented or non-cemented fixation.

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)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #:

510(k) Summary

Prepared on: 2026-06-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Stryker Corporation (Tornier, Inc.)
Applicant Address	10801 Nesbitt Avenue South Bloomington MN 55437 United States
Applicant Contact Telephone	612-258-5639
Applicant Contact	Ms. Jang Long
Applicant Contact Email	jang.long@stryker.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Tornier Perform Reversed Glenoid and Tornier Perform Reversed Augmented Glenoid Shoulder System
Common Name	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Classification Name	Shoulder Prosthesis, Reverse Configuration
Regulation Number	888.3660
Product Code(s)	PHX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K161742	Tornier Perform Reversed Glenoid and Tornier Perform Reversed Augmented Glenoid Shoulder System (previously branded as Aequalis PerFORM Reversed Glenoid and Aequalis PerFORM+ Reversed Glenoid, respectively)	PHX

Device Description Summary

21 CFR 807.92(a)(4)

The Tornier Perform Reversed Glenoid and Tornier Perform Reversed Augmented Glenoid Shoulder System is a modular reverse shoulder arthroplasty system composed of a Glenoid Component Assembly and a Humeral Component Assembly. This system replaces the shoulder joint to help reduce pain and restore shoulder mobility compared to the patient's preoperative condition.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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 the devices if sufficient bone stock remains

Notes:

- All components are single use.
- The glenoid sphere implant is anchored to the bone with screws and is for non-cemented fixation.
- All compatible humeral components are available for cemented or non-cemented fixation.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The intended use of the subject device, Tornier Perform Reversed Glenoid and Tornier Perform Reversed Augmented Glenoid Shoulder System, is the same as that of the predicate device, the Aequalis PerFORM Reversed Glenoid and Aequalis PerFORM+ Reversed Glenoid (K161742, K182696 and K213124). Both devices are intended for replacement of the shoulder joint to reduce pain and improve shoulder mobility in comparison with preoperative status. There are no differences in intended use that raise new questions of safety or effectiveness.

Technological Comparison 21 CFR 807.92(a)(6)

The Tornier Perform Reversed system included in this submission has the same core technological characteristics as the currently cleared Tornier Perform Reversed configurations, including intended use, fundamental scientific technology, materials, design principles, fixation method, and sterilization. The proposed changes introduce additional baseplate–glenosphere compatibility configurations and additive manufacturing updates without altering the core technology of the device.

Although additive manufacturing updates and expanded compatibility combinations were implemented, these changes do not alter device performance characteristics or introduce new risks. Any differences in technological characteristics were addressed through nonclinical bench testing conducted in accordance with applicable FDA-recognized consensus standards and previously established acceptance criteria.

Based on the comparison of technological characteristics and the supporting nonclinical performance and biocompatibility data, the Tornier Perform Reversed system is substantially equivalent to the currently cleared Tornier Perform Reversed configurations.

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

Nonclinical performance testing was conducted to support a determination of substantial equivalence for the proposed additional baseplate–glenosphere compatibilities within the Tornier Perform Reversed System. Testing was performed using applicable FDA guidance documents and FDA recognized consensus standards, with test methods and acceptance criteria consistent with those previously established for currently cleared Tornier Perform Reversed configurations.

Submitted and referenced testing includes:

- Range of motion analysis conducted in accordance with ASTM F1378
- Glenoid loosening testing performed per ASTM F2028
- Fatigue testing using previously established protocols to evaluate worst case baseplate–glenosphere configurations

Additional material property and characterization testing was performed, as applicable, to evaluate additive manufacturing updates and to confirm that these updates do not adversely affect device performance.

The results of the nonclinical testing demonstrate that the Tornier Perform Reversed System with the proposed changes meets applicable performance requirements and does not introduce new risks or new questions of safety or effectiveness. Collectively, these results support a determination of substantial equivalence.

No clinical studies were performed.

The nonclinical testing submitted and referenced in this 510(k), including bench performance testing and biocompatibility evaluation, demonstrates that the Tornier Perform Reversed system with the proposed additional baseplate–glenosphere compatibilities and additive manufacturing updates is as safe and effective as the currently cleared Tornier Perform Reversed configurations. Bench testing conducted in accordance with applicable FDA guidance and FDA-recognized consensus standards confirmed that the device meets established performance requirements and does not introduce different risks or different questions of safety or effectiveness. Biocompatibility was addressed through biological testing, chemical characterization with toxicological risk assessment, and risk-based evaluation in accordance with ISO 10993-1, demonstrating that the relevant biological endpoints are adequately addressed. No clinical testing was required for this submission, as the nonclinical data are sufficient to support a determination of substantial equivalence.