July 22, 2026

Tornier, Inc.
Stefanie Tarara
Principal Regulatory Affairs Specialist
10801 Nesbitt Ave. S.,
Bloomington, MN 55437 USA

Re: K260721
Trade/Device Name: Tornier Perform Advanced Glenoid
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: March 5, 2026
Received: June 22, 2026

Dear Stefanie Tarara:

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 -S

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.	K260721

Please provide the device trade name(s).

Tornier Perform Advanced Glenoid

Please provide your Indications for Use below.

Prosthetic replacement with the Tornier Perform Advanced Glenoid implants may be indicated to relieve severe pain or significant disability caused by:
• Degenerative pathologies: osteoarthritis and post-traumatic arthritis
• Revision surgery when other treatments or devices have failed if sufficient bone stock remains

Refer to the Indications for the compatible humeral systems. Tornier Perform Advanced Glenoid is compatible with the following humeral systems:
• Tornier Perform Humeral System - Stem
• Tornier Perform Humeral System - Stemless
• Tornier Perform Humeral System - Fracture
• Tornier HRS
• Tornier HRS Max
• Tornier Flex Shoulder System
• Tornier Simpliciti Shoulder System
• ReUnion Shoulder System

Tornier Perform Advanced Glenoid is intended for cemented use only.
Tornier Perform humeral components are intended for cemented and un-cemented use, except for stemless systems (Tornier Perform Humeral System - Stemless and the Tornier Simpliciti Shoulder System) which are intended for press-fit (un-cemented) use only.

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) #:

510(k) Summary

Prepared on: 2026-07-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Tornier, Inc.
Applicant Address	10801 Nesbitt Avenue South Bloomington MN 55437 United States
Applicant Contact Telephone	1-269-800-2754
Applicant Contact	Mrs. Stefanie Tarara
Applicant Contact Email	stefanie.tarara@stryker.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Tornier Perform Advanced Glenoid
Common Name	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Classification Name	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented
Regulation Number	888.3660
Product Code(s)	KWS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K160975	Tornier Perform Anatomic Augmented Glenoid (Aequalis PerFORM+ Shoulder System)	KWS
K111902	Tornier Perform Anatomic Glenoid	KWS
K201315	Tornier Perform Humeral System - Stem	KWT
K102670	Total Shoulder System	KWS
K091196	GRS Glenoid Resurfacing System	KWS
K202289	ReUnion Reversible Fracture System (RFX), ReUnion Reverse Shoulder Arthroplasty System (RSA), ReUnion Total Shoulder Arthroplasty System (TSA)	KWS

Device Description Summary

21 CFR 807.92(a)(4)

The Tornier Perform™ Advanced Glenoids have a bearing surface of Vitamin-E-blended UHMWPE and are designed as the next generation TSA glenoid component.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Prosthetic replacement with the Tornier Perform Advanced Glenoid implants may be indicated to relieve severe pain or significant disability caused by:

• Degenerative pathologies: osteoarthritis and post-traumatic arthritis

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Refer to the Indications for the compatible humeral systems. Tornier Perform Advanced Glenoid is compatible with the following humeral systems:
• Tornier Perform Humeral System - Stem
• Tornier Perform Humeral System - Stemless
• Tornier Perform Humeral System - Fracture
• Tornier HRS
• Tornier HRS Max
• Tornier Flex Shoulder System
• Tornier Simpliciti Shoulder System
• ReUnion Shoulder System

Tornier Perform Advanced Glenoid is intended for cemented use only.
Tornier Perform humeral components are intended for cemented and un-cemented use, except for stemless systems (Tornier Perform Humeral System - Stemless and the Tornier Simpliciti Shoulder System) which are intended for press-fit (un-cemented) use only.

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

The Tornier Perform Advanced Glenoid System indications for use align with those of the predicate devices.

The Tornier Perform Advanced Glenoid does not raise different questions of safety or effectiveness. Based upon a comparison of the intended use, materials, summary of technological characteristics, and non-clinical evaluation, the subject Tornier Perform Advanced Glenoid is substantially equivalent to the predicate devices: Tornier Perform Anatomic Augmented Glenoid (K160975) and Tornier Perform Anatomic Glenoid (K111902).

Technological Comparison 21 CFR 807.92(a)(6)

The technological differences between the subject and predicates devices are not significant as the general shape, fixation methods and articulation are similar. The subject device's shape, fixation features, and surgical preparation were shown to be substantially equivalent to the predicate through standardized anatomic glenoid loosening and mechanical benchtop testing. Testing was conducted for each fixation variant with worst-case component sizes tested.
The Subject device is manufactured with a highly cross-linked Vitamin-E-blended UHMWPE. The same VE-UHMWPE material is used with Perform Humeral Reversed Inserts (K201315).

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

Non-clinical testing was performed to demonstrate substantial equivalence to the predicate device.
• Glenoid Loosening
• Glenoid Wear
• Range of motion testing
• Biocompatibility evaluation
• Packaging and shelf-life evaluations
• Distribution testing
• Sterilization evaluation
• Endotoxin testing
• MRI compatibility evaluation

No clinical studies were performed.

The Tornier Perform Advanced Glenoid System does not raise different questions of safety or effectiveness. Differences in technological characteristics have been addressed with performance testing. The results of performance testing for the Tornier Perform Advanced Glenoid supports substantial equivalence to the predicate Tornier Perform Anatomic Augmented Glenoid (K160975, cleared on June 10, 2016).