January 8, 2026

Tornier, Inc
Lamia Askri
Senior Staff Regulatory Affairs specialist
10801 Nesbitt Avenue South
Bloomington, Minnesota 55437

Re: K252788
Trade/Device Name: Tornier Perform™ Reversed Monopost Glenoid (Perform Mono)
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: December 2, 2025
Received: December 4, 2025

Dear Lamia Askri:

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

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. | K252788 |

Please provide the device trade name(s).

Tornier Perform™ Reversed Monopost Glenoid (Perform Mono)

Please provide your Indications for Use below.

The Tornier Perform™ Reversed MonoPost 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 native glenoid bone remains

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

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

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

510(k) #: K252788

# 510(k) Summary

Prepared on: 2026-01-07

## 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 | +33685225479 |
| Applicant Contact | Mrs. Lamia Askri |
| Applicant Contact Email | lamia.askri@stryker.com |

## Device Name

21 CFR 807.92(a)(2)

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

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K161742 | Aequalis Perform Reversed and Aequalis PerFORM+ Reversed Glenoid | PHX, KWS |
| K211359 | Shoulder iD Primary Reversed Glenoid | PHX, KWS |
| K061439 | Aequalis Reversed Prosthesis | PHX, KWS |
| K173900 | Arthrex Univers Revers Modular Glenoid System | PHX |

## Device Description Summary

21 CFR 807.92(a)(4)

The Tornier Perform™Reversed MonoPost Glenoid (Perform Mono) 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)

The Tornier Perform™ Reversed MonoPost 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 native glenoid bone remains

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

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The Tornier Perform™ Reversed MonoPost Glenoid indications for use align with those of the predicate devices.

## Technological Comparison

21 CFR 807.92(a)(6)

The Tornier Perform™ Reversed MonoPost Glenoid and the predicates have the same intended use, similar principle of operation and same technological features. Differences for the subject Tornier Perform™ Reversed MonoPost Glenoid include an additional range of glenoid baseplates with metallic augmentation, baseplates for BIO-RSA technique and associated instruments to accommodate specific patterns of glenoid wear in patients.

## Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical testing was performed to demonstrate substantial equivalence to the Tornier Perform reversed Glenoid and Tornier Perform Reversed Augmented Glenoid predicate device (K161742):
• Fatigue testing
• Pull out testing
• Loosening Testing
• Range of motion evaluation
• Biocompatibility evaluation
• Cadaveric Lab
• Packaging and shelf-life evaluations
• Sterilization evaluation
• MRI compatibility evaluation
• Fretting Corrosion evaluation

No clinical studies were performed.

Tornier Perform Reversed MonoPost Glenoid 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 Perform Mono support substantial equivalence to the predicate Tornier Perform Reversed Glenoid and Tornier Perform Reversed Augmented Glenoid (K161742).