December 29, 2025

Toetal Solutions
% Danielle Besal
Principal Consultant
MRC Global, LLC
9085 E. Mineral Circle,
Suite 110
Centennial, Colorado 80112

Re: K253325
Trade/Device Name: ZipToe™ Hammertoe Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: September 29, 2025
Received: September 30, 2025

Dear Danielle Besal:

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma 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.	K253325

Please provide the device trade name(s).

ZipToe™ Hammertoe Fusion System

Please provide your Indications for Use below.

The ZipToe™ Hammertoe Fusion System is indicated for interphalangeal fusion of the toes.

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) #: K253325

510(k) Summary

Prepared on: 2025-09-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Toetal Solutions
Applicant Address	7 Great Valley Parkway Suite 295 Malvern PA 19355 United States
Applicant Contact Telephone	610-952-0462
Applicant Contact	Mr. Bill Rhoda
Applicant Contact Email	rhoda@runwayhc.com
Correspondent Name	MRC Global LLC
Correspondent Address	9085 East Mineral Circle Suite 110 Centennial CO 80112 United States
Correspondent Contact Telephone	9018278670
Correspondent Contact	Danielle Besal
Correspondent Contact Email	danielle.besal@askmrcglobal.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ZipToe™ Hammertoe Fusion System
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Pin, Fixation, Smooth
Regulation Number	888.3040
Product Code(s)	HTY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201715	Stryker Smart Toe II	HTY
K050259	Arthrex Bio-Pin	HTY

Device Description Summary

21 CFR 807.92(a)(4)

The ZipToe™ Hammertoe Fusion System is a permanent implant designed for fixation of the proximal interphalangeal joint. The device is composed of a titanium alloy sleeve (ASTM F136) with two interior deployable nitinol claws (ASTM F2063). The implant is available in multiple sizes to accommodate varying patient anatomy. The insertion tool for the implant includes two "ripcords" that are pulled to deploy the implant's claws. The "ripcord" is a surgical suture that is connected to the implant's claws through a loop; thus, once the implant is in place, the ends of the suture ("ripcords") are pulled to deploy the claws. Once deployed, the claws assist in initial fixation by providing opposing compression into the bone and help minimize implant rotation.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The ZipToe™ Hammertoe Fusion System is indicated for interphalangeal fusion of the toes.

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

The subject devices are substantially equivalent to the Stryker Smart Toe II (K201715). The subject devices are identical in indications for use.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device is similar in technological characteristics to the predicate device. The subject and predicate devices are similar in geometry in that both are an intramedullary design as well as similar in sizing and materials to the predicate device. The minor differences in technological characteristics do not introduce any different questions of safety or effectiveness.

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

Mechanical testing of the subject device including static 4-point bending, static pushout, static torsion, dynamic 4-point bending, fretting corrosion, pitting corrosion testing per ASTM F2129, and biocompatibility evaluation per ISO 10993-1 have been performed to evaluate the ZipToe™ Hammertoe Fusion System.

Clinical data are not applicable.

The results confirm that the subject device is substantially equivalent to the predicate device.