February 25, 2021

Treace Medical Concepts, Inc.
% Dawn Norman
Executive Vice President
MRC-X, LLC
6075 Poplar Avenue
Suite 500
Memphis, Tennessee 38119

Re: K183363
Trade/Device Name: Treace Medical Concepts (TMC) Snap-Off Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC

Dear Dawn Norman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 13, 2019. Specifically, FDA is updating this SE Letter to correct a typo in the trade name identified on the previous SE Letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shumaya Ali, MPH, OHT6: Office of Orthopedic Devices, (301)796-2356, Shumaya.Ali@fda.hhs.gov.

Sincerely,

Shumaya Ali -S

Shumaya Ali, MPH
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

June 13, 2019

Treace Medical Concepts, Inc.
% Dawn Norman
Executive Vice President
MRC-X, LLC
6075 Poplar Avenue,
Suite 500
Memphis, Tennessee 38119

Re: K183363
Trade/Device Name: Treace Medical Concepts (TMC) Plating System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 9, 2019
Received: May 13, 2019

Dear Dawn Norman:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, MPH
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183363

Device Name

Treace Medical Concepts, Inc (TMC) Snap-Off Screw System

Indications for Use *(Describe)*

The Treace Medical Concepts, Inc (TMC) Snap-Off Screw System is intended for use for adult and pediatric patients, as indicated for small or long bones requiring fixation of fractures, fracture repair, revision procedures, joint fusions (arthrodesis), bone reconstructions, osteotomy, ligament fixation, and pseudoarthrosis (non-unions) of bones, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, phalanges, ulnar styloid, capitellum, radial head and radial styloid.

In the foot, the following specific examples are indicated with screws appropriate for the size of the device:

- mono or bicortical osteotomies
- distal or proximal metatarsal osteotomies
- weil osteotomy
- fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)
- Akin type osteotomy

Not for spinal use.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Treace Medical Concepts, Inc (TMC) Snap-Off Screw System

June 10, 2019

K183363

Company: Treace Medical Concepts, Inc.
203 Fort Wade Rd., Suite 150
Ponte Vedra, FL 32081

Primary Contact: Dawn Norman
Executive Vice President, MRC|X, LLC
Phone: 618.604.3064
dawn.norman@mrc-x.com

Company/Secondary Contact: Rachel Osbeck
Vice President, Quality Assurance
Treace Medical Concepts, LLC
Phone: 904.373.5940 Ext. 1304
rosbeck@treace.net

Trade Name: **Treace Medical Concepts, Inc (TMC) Snap-Off Screw System**

Common Name: Screw, Fixation, Bone

Classification: Class II

Regulation Number: 21 CFR 888.3040 (Smooth or threaded metallic bone fixation fastener)

Panel: 87- Orthopedic

Product Code: HWC

Device Description:

The Treace Medical Concepts, Inc (TMC) Snap -Off Screw System includes self-drilling and self-tapping screws provided in diameters of 2.0mm (lengths 10mm-20mm) and 2.7mm(lengths 8mm-20mm).

The screws are composed of titanium alloy conforming to ASTM F136.

Indications for Use:
The Treace Medical Concepts, Inc (TMC) Snap-Off Screw System is intended for use for adult and pediatric patients, as indicated for small or long bones requiring fixation of fractures, fracture repair, revision procedures, joint fusions (arthrodesis), bone reconstructions, osteotomy, ligament fixation, and pseudoarthrosis (non-unions) of bones, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, phalanges, ulnar styloid, capitellum, radial head and radial styloid.

In the foot, the following specific examples are indicated with screws appropriate for the size of the device:

- mono or bicortical osteotomies
- distal or proximal metatarsal osteotomies
- weil osteotomy
- fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)
- Akin type osteotomy

Not for spinal use.

Substantial Equivalence:

Device	**Subject** **Treace Medical Concepts, Inc (TMC) Snap-Off Screw System**	**Primary Predicate** **Integra SPIN Snap-Off Screw (K991477)**	**Secondary Predicate** **TMC Compression Screw System (K172617)**
Intended Use/ Indications for Use	The TMC Snap-Off Screw System is intended for use for adult and pediatric patients, as indicated for small or long bones requiring fixation of fractures, fracture repair, revision procedures, joint fusions (arthrodesis), bone reconstructions, osteotomy, ligament fixation, and pseudoarthrosis (non-unions) of bones, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, phalanges, ulnar styloid, capitellum, radial head and radial styloid. In the foot, the following specific examples are indicated with screws appropriate for the size of the device:	The Integra SPIN Snap-Off Screw is indicated for fixing the elective osteotomies of the mid-foot bones and the metatarsal and phalanges of the foot. Examples include: -Weil Osteotomy -Unicortical small bone fixation	The TMC Compression Screw System is intended for use for adult and pediatric patients, as indicated for small or long bones requiring fixation of fractures, fracture repair, revision procedures, joint fusions (arthrodesis), bone reconstructions, osteotomy, ligament fixation, and pseudoarthrosis (non-unions) of bones, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, phalanges, patella, ulnar styloid, capitellum, radial head and radial styloid. In the foot, the following specific examples are indicated with screws appropriate for the size of the device: • mono or bicortical osteotomies • distal or proximal metatarsal osteotomies • weil osteotomy

Device	Subject Treace Medical Concepts, Inc (TMC) Snap-Off Screw System	Primary Predicate Integra SPIN Snap-Off Screw (K991477)	Secondary Predicate TMC Compression Screw System (K172617)
	• mono or bicortical osteotomies • distal or proximal metatarsal osteotomies • weil osteotomy • fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.) • Akin type osteotomy Not for spinal use.		• fusion of the metatarsalphalangeal joint • fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.) • Akin type osteotomy • talonavicular fusions • cuboid fusions Not for spinal use.
Material	Ti-6-4; ASTM F136	Titanium Alloy	Ti-6-4; ASTM F136
Finish	Type III Titanium Color Anodization	Titanium Color Anodization	Type III Titanium Color Anodization

Performance Testing:
Performance testing was performed to evaluate the torsion and pull-out properties of the subject device in accordance with ASTM F543. This testing confirmed the subject screws to be substantially equivalent to the predicate Integra SPIN Snap-Off Screw.

Conclusion:
The subject Treace Medical Concepts, Inc (TMC) Snap-Off Screw System components were demonstrated to be substantially equivalent with respect to indications for use, design, dimension, and materials to the following device, previously cleared by the FDA:

- Primary Predicate: Integra SPIN Snap-Off Screw (K991477)
- Secondary Predicate: Treace Medical Concepts, Inc (TMC) Compression Screw System (K172617)

The subject intended use and indications for use are a subset of the secondary predicate intended use and indications for use to ensure only clinically appropriate uses are defined for the design and sizes of the subject screws. The material and overall geometry for the predicate devices are substantially equivalent to those of the subject device.