July 18, 2023

Forma Medical, Inc.
% Kyle Kovach
Sr. Quality and Regulatory Engineer
JALEX Medical
27865 Clemens Rd Suite 3
Westlake, Ohio 44145

Re: K230945
Trade/Device Name: Forma Medical Headless Compression Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 16, 2023
Received: June 16, 2023

Dear Kyle Kovach:

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,

FDA Tejen D. Soni -S

For
Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230945

Device Name

Forma Medical Headless Compression Screw

Indications for Use *(Describe)*

Forma Medical Headless Compression Screws are indicated for fixation of intra-articular and extra articular fractures, avulsions, non-unions, and osteotomies of small bones and small bone fragments; as well as arthrodesis of small joints.

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.

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510(k) Summary

Submitted By: Forma Medical, Inc.
3401 Hartzdale Drive
Suite 103B, Unit #611
Camp Hill, PA 17011

Date: 07/11/2023

Contact Person: Kyle Kovach, Sr. Quality and Regulatory Engineer, JALEX Medical
Contact Telephone: (440) 787-5832
Contact Fax: (440) 933-7839

Device Trade Name: Forma Medical Headless Compression Screw
Common Name: Screw, Fixation, Bone
Device Classification Name: Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Device Classification: Class II
Reviewing Panel: Orthopedic
Product Code: HWC
Primary Predicate Device: Synthes (USA) 1.5mm Headless Compression Screws (K090949)
Reference Devices: Globus Medical CAPTIVATE™ Compression Screws (K162825)
OsteoMed ExtremiFix Mini & Small Cannulated Screw System (K202680)

Device Description:

Forma Medical Headless Compression Screws are designed to hold bones in relative stability for fracture fixation and arthrodesis. The screws are available in multiple diameters and lengths based on patient anatomy and clinical application. The screws are manufactured from titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1537, and F138. The system includes screws and instruments. The system instrumentation is manufactured from stainless steel, aluminum, and other surgical grade materials.

Indications for Use:

Forma Medical Headless Compression Screws are indicated for fixation of intra-articular and extra articular fractures, avulsions, non-unions, and osteotomies of small bones and small bone fragments; as well as arthrodesis of small joints.

Summary of Technological Characteristics:

The Forma Medical Headless Compression Screw and the predicates have the same intended use and fundamental scientific technology. All devices compare similarly in:

- Design features
- Intended use
- Materials
- Dimensions
- Function

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Technological Characteristics Comparison

Item	Forma Medical Headless Compression Screw	Synthes (USA) 1.5mm Headless Compression Screws (K090949)	Globus Medical CAPTIVATE™ Compression Screws (K162825)	OsteoMed ExtremiFix Mini & Small Cannulated Screw System (K202680)	Comparison
Classification Name	Smooth or threaded metallic bone fixation fastener	Smooth or threaded metallic bone fixation fastener	Smooth or threaded metallic bone fixation fastener	Smooth or threaded metallic bone fixation fastener	Equivalent
Regulation	888.3040	888.3040	888.3040	888.3040	Equivalent
Product Code	HWC	HWC	HWC	HWC, HTN	Equivalent
Indications for Use	Forma Medical Headless Compression Screws are indicated for fixation of intra-articular and extra articular fractures, avulsions, non-unions, and osteotomies of small bones and small bone fragments; as well as arthrodesis of small joints.	Synthes 1.5mm Headless Compression Screws are indicated for fixation of intra-articular and extra-articular fractures, avulsions, non-unions, and osteotomies of small bones and small bone fragments; as well as arthrodesis of small joints.	CAPTIVATE™ Compression Screws are indicated for use in adult and pediatric patients, for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device. CAPTIVATE™ VL Compression Screws are indicated for use in adult and pediatric patients, for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of the phalanges, metacarpals, carpals, metatarsals, midfoot, hind foot, ankle, fibula, distal tibia, proximal tibia, radius, ulna, humerus, and clavicle.	The Osteomed ExtremiFix Mini & Small Cannulated Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.	Equivalent to primary predicate
Description	Forma Medical Headless Compression	The Synthes 1.5mm Headless Compression	CAPTIVATE™ Compression Screws consist of	The OsteoMed Mini & Small Cannulated Screw	Substantially Equivalent

	Screws are designed to hold bones in relative stability for fracture fixation and arthrodesis. The screws are available in multiple diameters and lengths based on patient anatomy and clinical application. The screws are manufactured from titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1537, and F138. The system includes screws and instruments. The system instrumentation is manufactured from stainless steel, aluminum, and other surgical grade materials.	Screws are solid bone fixation screws featuring a partially threaded shaft and threaded head. The screws are available in stainless steel and titanium.	bone screws designed to compact juxtaposed bone for reconstruction and enhanced arthrodesis. The implants are available in various diameters and lengths to accommodate patient anatomy, with headless, partially or fully threaded, solid or cannulated, and variable length (VL) options. CAPTIVATE™ implants are manufactured from titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F1537 and F138.	System is comprised of screws and washers used for bone fixation of the hand and foot following trauma or osteotomy. The System features cannulated screws in the following dimensions: 2.0mm screw diameter- 6mm to 42mm screw length; 2.4mm screw diameter- 6mm to 50mm screw length; 3.0mm screw diameter- 10mm to 40mm screw length; 4.0mm screw diameter- 12mm to 52mm screw length; The system instruments include depth gauges, screwdrivers, countersinks, guide wires, and other instruments to facilitate the placement of screws. The implants (screws and washers) of the OsteoMed Mini & Small Cannulated Screw System are made from titanium alloy (ASTM F136).	
Material	Titanium Alloy, Cobalt Chromium Molybdenum Alloy, and	Titanium alloy, stainless steel	Titanium Alloy, Cobalt Chromium Molybdenum Alloy, and	Titanium alloy per ASTM F136	Equivalent to Globus reference predicate

	Stainless steel per ASTM F136, F1537, and F138		Stainless steel per ASTM F136, F1295, F1472, F1537, and F138		
Lengths	Ø1.5 mm: 9-20 mm Ø2.0 mm: 10-42 mm Ø2.5 mm: 10-50 mm Ø3.0 mm: 12-40 mm Ø4.0 mm: 14-52 mm	Ø1.5 mm: 9-20 mm	Ø2.5 mm: 9-40 mm Ø3.0 mm: 10-40 mm Ø4.0 mm: 16-60 mm	Ø2.0 mm: 6-42 mm Ø2.5 mm: 6-50 mm Ø3.0 mm: 10-40 mm Ø4.0 mm: 12-52 mm	Ø1.5 mm equivalent to primary predicate and Ø2.0-4.0 mm equivalent to OsteoMed reference predicate
Cannulation	Ø1.5 mm: Solid Ø2.0-4.0 mm: Cannulated	Solid	Solid and cannulated	Cannulated	Ø1.5 mm equivalent to primary predicate and Ø2.0-4.0 mm equivalent to OsteoMed reference predicate

Mechanical Testing:

Substantial equivalence is supported by mechanical evaluation and testing compared to the predicate devices in torsional strength, insertion/removal torque, and pullout strength per ASTM F543.

Conclusion:

Based on the indications for use, technological characteristics, and comparison with the predicate devices, the subject device has demonstrated substantial equivalence.