July 13, 2018

Biedermann Medtech, Inc.
Michelle Montesino
Regulatory Affairs Specialist
7620 NW 25th Street
Unit 3 & 4
Miami, Florida 33122

Re: K173556
Trade/Device Name: Injection 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 8, 2018
Received: June 11, 2018

Dear Michelle Montesino:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K173556

Device Name
Injection Screw

Indications for Use *(Describe)*

The MDS Injection Screw is intended for the fixation of bone fractures and bone reconstructions of the humerus. The MDS Injection Screws can be used to deliver injectable bone void fillers to a surgical site and are compatible with applicable MDS plating systems.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

Submitter Name: Biedermann Medtech, Inc.

Submitter Address: 7620 NW 25th Street, Unit 3 & 4;
Miami, FL 33122

Contact Person: Michelle Montesino
Phone: (786) 422-1400 Ext. 106
Fax: (786) 422-1401

Anderson Giraldo
Phone: (786) 422-1400 Ext 115
Fax: (786) 422-1401

Date of Submission: 07/12/2018

Manufacturer Name: Biedermann Medtech, Inc.

Manufacturer Address: 7620 NW 25th Street, Unit 3 & 4;
Miami, FL 33122

Registration Number: 3013248720

Contact Name: Markku Biedermann

Title: Chairman

Device Trade Name: Injection Screw

Device Common Name: Primary: Screw, Fixation, Bone

Classification Names: Primary: Screw, Fixation, Bone

Classification Code: Primary: HWC – Class II

Classification Panel: Orthopedic

Regulation Number: Primary: 21 CFR section 888.3040 – Smooth or threaded metallic bone fixation fastener

Predicate Device:

Primary	K142776	Flow-Fx Flow-Screw
Secondary	K151146	N-Force Fixation System
Secondary	K161058	Miami Device Solutions Cannulated Screw
Secondary	K132502, K140769	Variax 2 System Bone Screws

Reference Devices: Paragon 28, Inc.; The Monster Screw System: Instrument Reprocessing Instructions for Reusable Instruments – K151418

Miami Device Solutions, LLC; Distal Radius Plating System – K161292/K162635

Etex Corp., Beta-bsm Injectable Bone Substitute Material – K101557

Miami Device Solutions Proximal Humerus Plating System Multiuse Screw – K141493

Device Description:
Miami Device Solutions (MDS) Injection Screws enable stable fixation of simple and complex fractures of the humerus. The MDS Injection Screws are only to be used in combination with compatible MDS 3.5T plating systems in the humerus (Proximal Humerus Plating System, K141493/K161058; MDS Plating System, K172786). When inserted through a 3.5T plate screw hole, injection screw placement is possible at any angle within a 40° cone. MDS Injection Screws can be used with or without bone void fillers. Fenestrations along the screw length allow bone void filler delivery directly into the surgical site.

Materials: Titanium alloy.

Intended Use:
The MDS Injection Screw is intended for the fixation of bone fractures and bone reconstructions of the humerus. The MDS Injection Screws can be used to deliver injectable bone void fillers to a surgical site and are compatible with applicable MDS plating systems.

Substantial Equivalence Statement:
Documentation is provided which demonstrates that the MDS Injection Screw is equivalent to its predicate in terms of material, design, intended use, and performance characteristics.

Performance Data:

Non-Clinical Performance and Conclusions:

The results of non-clinical (laboratory/performance) testing as well as engineering analysis such as the following for subject devices demonstrate that the device is as safe and as effective as the predicates:

- Mechanical Performance Testing
  - ASTM F543 Standard Specification and Test Method for Metallic Bone Screws
  - Angular Stability
  - Fatigue Strength
- BVF Delivery
  - Cadaver Lab
  - Injectability/Extrudability/Extraction Torque
  - BVF Characterization

Substantial equivalence is demonstrated in the performance testing section of the submission by comparing subject and predicate designs. Comparison of the design, intended use, and testing demonstrate that the MDS Injection Screw performs as well as the predicate devices and should thereby be considered substantially equivalent.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

Conclusion
The MDS Injection Screw is substantially equivalent to the predicate devices.