DT MedTech LLC
% Marcos Velez-Duran
President
M Squared Associates, Inc
575 8th Avenue, Suite 1212
New York, New York 10018

November 7, 2017

Re: K171004
Trade/Device Name: Hintermann Series H2 Total Ankle System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: October 11, 2017
Received: October 12, 2017

Dear Marcos Velez-Duran:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Katherine D. Kavlock -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171004

Device Name
Hintermann Series H2 Total Ankle System

Indications for Use *(Describe)*

The Hintermann Series H2 Total Ankle Replacement (Hintermann Series H2) system is designed to treat ankle arthritis through replacement of the ankle joint with a prosthesis, thereby reducing pain, restoring alignment, replacing flexion and extension movement in the ankle joint, and allowing for movement at the replaced joint.

The Hintermann Series H2 is indicated as a total ankle replacement in primary or revision surgery of ankle joints damaged by:

- Systemic arthritis of the ankle (e.g., rheumatoid arthritis, hemochromatosis)
- Primary arthritis (e.g., degenerative disease)
- Secondary arthritis (e.g., post-traumatic, avascular necrosis, provided enough of the talus is preserved to support the implant)

The Hintermann Series H2 is also indicated for patients with a failed previous ankle surgery and revision surgeries following failed total ankle replacement or non-union/mal-union of the ankle arthrodesis, provided sufficient bone stock is present.

Note: In the United States, this device is intended for cemented use only.

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
Hintermann Series H2 Total Ankle System
K171004

Sponsor: DT MedTech, LLC.
110 West Road
Suite 227
Towson, MD 21204

Contact: Shawn T. Huxel
Executive Vice President
Phone: 410-427-0003
Fax: 410-494-0515

Date Prepared: November 1, 2017

Trade Name: **Hintermann Series H2™ Total Ankle System**

Common Name: Total ankle prosthesis

Classification: 888.3110 Ankle joint metal/polymer semi-constrained cemented prosthesis.

Product Code: HSN

Predicate Devices: Integra (Cadence) Total Ankle Replacement System, Integra LifeSciences, Inc., K151459

INBONE I and II Total Ankle Replacement, Wright Medical Technologies, K051023, K100886, K123059, K133585

Salto Talaris Total Ankle Prosthesis, Integra LifeSciences, Inc., K060544, K090076, K130533, K153452

Exactech Vantage Total Ankle System, Exactech Inc., K152217

Description of Device:

The Hintermann Series H2 Total Ankle System includes a metal tibial component, polyethylene inlay, and metal talar component. The tibial and talar components are coated with plasma spray titanium on the bone contacting surfaces. The system is a semi-constrained device used for the indications as follows.

Hintermann Series H2 Total Ankle System K171004
510(k) Summary

Indications for Use:

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The Hintermann Series H2 is also indicated for patients with a failed previous ankle surgery and revision surgeries following failed total ankle replacement or non-union/mal-union of the ankle arthrodesis, provided sufficient bone stock is present. Note: In the United States, this device is intended for cemented use only.

Comparison of Technological Characteristics with the Predicate Device:

The technological characteristics for the Hintermann Series H2 Total Ankle System are the similar to, or the same as, the characteristics of the predicate devices as outlined in the table that follows.

	Hintermann Series H2	Vantage	Cadence	Inbone II	Salto Talaris
Manufacturer	DT MedTech	Exactech	Integra Life Sciences	Wright Medical Technology, Inc	Tornier
Submission number	K171004	K152217	K151459	K051023 K100886 K123059 K133585	K060544 K090076 K130533 K153452
Indications for use	Total ankle replacement	Total ankle replacement	Total ankle replacement	Total ankle replacement	Total ankle replacement
Method of fixation	Cemented	Cemented	Cemented	Cemented	Cemented
Sterilization method	Gamma	Gamma	Gamma	Gamma	Gamma

Hintermann Series H2 Total Ankle System K171004
510(k) Summary

	Hintermann Series H2	Vantage	Cadence	Inbone II	Salto Talaris
Materials					
Tibial component	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy	CoCr alloy
Poly insert	UHMWPE	UHMWPE	UHMWPE	UHMWPE	UHMWPE
Talar component	CoCr alloy	CoCr alloy	CoCr alloy	CoCr alloy	CoCr alloy
Coating	Titanium plasma spray	Porous titanium coating	Porous titanium coating	Titanium plasma spray	Titanium plasma spray
Sizes					
Tibial component	5 sizes (2, 3, 4, 5, 6)	Not reported	9 sizes (1, 1X, 2, 2X, 3, 3X, 4, 4X, 5)	9 sizes (size 2, 2L, 3, 3L, 4, 4L, 5, 5L, 6)	4 sizes (0, 1, 2, 3)
Poly insert	6 sizes (1, 2, 3, 4, 5, 6)	Not reported	5 sizes (1, 2, 3, 4, 5)	5 sizes (1+, 2, 3, 4, 5)	5 sizes (size 00, 0, 1, 2, 3)
Talar component	Std: 6 sizes (1, 2, 3, 4, 5, 6) Flat cut: 5 sizes (1, 2, 3, 4, 5)	Not reported	5 sizes (1, 2, 3, 4, 5)	5 sizes (1, 2, 3, 4, 5)	4 sizes (0, 1, 2, 3)

Nonclinical Testing Summary:
Following is a summary of the non-clinical testing that was conducted:

- Coating characterization per FDA *Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements* dated February 2, 2000
- Range of motion analysis per ASTM F2665
- Fatigue testing per ASTM F2665
- Contact area/contact stress analysis per ASTM F2665
- Constraint testing per ASTM F2665
- Tibial Component locking mechanism testing
- Wear testing per ASTM F2665
- Endotoxin testing per FDA guidance

Substantial Equivalence:

The design features of the Hintermann Series H2 Total Ankle System are substantially equivalent to the design features of other predicate devices previously cleared for market. The methods used to establish equivalence are based on the comparison of the intended use, product technical characteristics and performance characteristics as defined by ASTM F2665 Standard Specification for Total Ankle Replacement Prosthesis. All comparisons

confirmed that the Hintermann Series H2 Total Ankle System is substantially equivalent to the predicate devices. The safety, effectiveness, and performance of the Hintermann Series H2 Total Ankle System are adequately supported by the substantial equivalence information, material information and analysis data provided within this Premarket Notification. Therefore, it is concluded that the Hintermann Series H2 Total Ankle System is substantially equivalent to the noted predicate devices.

Conclusions:

While the Hintermann Series H2 Total Ankle System is not identical to the predicate devices, any differences that may exist do not significantly affect device safety and effectiveness. In addition, the differences do not add new or increased risks and complications. Therefore, it is concluded that the Hintermann Series H2 Total Ankle System is substantially equivalent to the predicate devices as outlined previously.