DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Arthrosurface, Inc.
Ms. Dawn Wilson
VP, Quality & Regulatory
28 Forge Parkway
Franklin, Massachusetts 02038

March 3, 2017

Re: K170350
Trade/Device Name: ToeMATE® Hammertoe Correction System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: March 1, 2017
Received: March 3, 2017

Dear Ms. Wilson:

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 and Part 809); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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)*
K170350

Device Name
ToeMATE® Hammertoe Correction System

Indications for Use *(Describe)*
Indicated for small bone fusion, fractures and inter-digital fusion of the fingers, toes and small bones.

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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"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."

Special 510(k): Device Modification

ToeMATE® Hammertoe Correction System

510(k) Owner:
Arthrosurface, Inc.
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Franklin, MA 02038
Tel: 508.520.3003
Fax: 508.528.4604

Contact:
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Establishment Registration Number: 3004154314

Date of Preparation: February 01, 2017

Confidentiality: Reference Section 3

Proprietary Name: ToeMATE® Hammertoe Correction System
Common Name: Screw, Fixation, Bone

Regulation Description: Smooth or Threaded Metallic Bone Fixation Fastener
Regulation Number: 21 CFR 888.3040
Device Class: Class II
Review Panel: Orthopedic
Product Code: HWC

Indications for Use

Indicated for small bone fusion, fractures and inter-digital fusion of the fingers, toes and small bones.

Device Description

The ToeMATE® Hammertoe Correction System consists of two intramedullary bone screws, a taper lock pin and a set of instruments used for implant site preparation and delivery. The implants are offered in three size options, x-small, small and large. The taper lock pin provides a press fit connection between the two screws with light contact pressure and is available in straight and angled configurations. The implant components are manufactured using implant grade titanium alloy and cobalt-chrome alloy.

Substantial Equivalence Information

Arthrosurface, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the additional sizes for the ToeMATE® Hammertoe Correction System are substantially equivalent in indications and design principles to the following predicate and/or reference devices, which have been previously cleared by the FDA:

Primary Predicate

K130859 Arthrosurface, Inc.'s Hammertoe Correction System

Additional Predicate(s)

K101165 Wright Medical PRO-TOE™ VO Hammertoe Implant System
K120645

The fundamental scientific technology of the proposed device has not changed relative to the predicate devices.

- Has the same Indications for Use,
- Uses the same operating principle,
- Is manufactured using common orthopedic implant materials,
- Utilizes similar instrumentation for proper placement,
- Is packaged and sterilized using the same materials and processes.

In support of this submission, the following non-clinical tests and/or analysis were performed for the Subject Device:

- Device Comparative Analysis
- Mechanical Testing: static and dynamic cantilever bending, torque to failure, insertion/removal torque, axial pullout and disassembly
- A Kinetic Chromogenic LAL Test on the finished product which meets the standard limit of 0.5 EU/mL or 20 EU/ Device per United States Pharmacopeia (USP) Chapter <85> Bacterial Endotoxins Test, USP Chapter <161> Transfusion and Infusion Assemblies and Similar

Medical Devices, and AAMI ST72:2002/R2010, Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing.

Conclusions

The results have demonstrated that the ToeMATE® Hammertoe Correction System is substantially equivalent to the predicate devices.