



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

HNM Total Recon, LLC
% Craig Pagan
Consultant
D2D Development, LLC
1135 W NASA Blvd.
Melbourne, Florida 32901

July 24, 2017

Re: K163486

Trade/Device Name: DRACO Locking Screws;
DRACO Compression Screws;
DRACO MetaFuse L Plates and the DRACO MetaFuse BLP Plates;
DRACO MetaFuse MTP Plates, Takú Plates, DuoTakú Plates, Open
Wedge Plates, Osteoplate Plates, Plantar Plates, Calcaneus Offset
Locking Plates

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And
Accessories

Regulatory Class: Class II

Product Code: KTT, HWC, HRS, HTY

Dated: June 20, 2017

Received: June 23, 2017

Dear Craig Pagan:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), 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

Indications for Use

510(k) Number (if known)

K163486

Device Name

DRACO Locking Screws

Indications for Use (Describe)

The DRACO Locking Screws are intended to be used in combination with DRACO Locking plates for adult and pediatric patients as indicated for small bone fracture fixation. Indications for use include fixation of fractures, osteotomies, non-unions of the clavicle, scapula, olecranon, radius, ulna, fibula, metacarpals, metatarsals, Hallux Valgus osteotomy corrections, middle hand and middle foot bones, particular in osteopenic bone.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Indications for Use

510(k) Number (if known)

K163486

Device Name

DRACO Compression Screws

Indications for Use (Describe)

The DRACO Compression Screws are indicated for fracture fixation and reconstruction of various bones, including, osteotomies in the foot (as Hallux Valgus treatment) or hand, arthrodesis in hand, foot or ankle surgery, fixation of bone fragments in long bones or small bone fractures. The size of the chosen screw should be adapted to the specific indication.

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)

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Indications for Use

510(k) Number (if known)

K163486

Device Name

DRACO MetaFuse L Plates and the DRACO MetaFuse BLP Plates

Indications for Use (Describe)

The DRACO MetaFuse L Plates and the DRACO MetaFuse BLP Plates are used for adult and pediatric patients as indicated for small bone fracture fixation. Indications for use include fixation of fractures, osteotomies, non-unions of the clavicle, scapula, olecranon, radius, ulna, fibula, metacarpals, Hallux Valgus osteotomy corrections, middle hand and middle foot bones, particular in osteopenic bone.

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)

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Indications for Use

510(k) Number (if known)

K163486

Device Name

DRACO MetaFuse MTP Plates, Takú Plates, DuoTakú Plates, Open Wedge Plates, Osteoplate Plates, Plantar Plates, Calcaneus Offset Locking Plates

Indications for Use (Describe)

The DRACO MetaFuse MTP Plates, Takú Plates, DuoTakú Plates, Open Wedge Plates, Osteoplate Plates, Plantar Plates, Calcaneus Offset Locking Plates can be used for adult and pediatric patients. Indications for use include fixation of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes.

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)

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