DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Summit Medical Ltd.
Sam Drew
RA Manager - Projects
Bourton Industrial Park
Bourton on the Water, Gloucestershire
GL54 2HQ
United Kingdom

July 25, 2017

Re: K170388
Trade/Device Name: ANCHORMAN Tibial Ligament Fixation Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 14, 2017
Received: June 14, 2017

Dear Sam Drew:

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

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)*
K170388

Device Name
ANCHORMAN Tibial ligament fixation device

Indications for Use *(Describe)*
Tibial fixation of biological ligament during orthopaedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) reconstruction

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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510(k) Summary – K170388
Summit Medical Ltd ANCHORMAN

SUMMIT MEDICAL
SURGICAL PRODUCTS

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Name of device	ANCHORMAN cortical tibial fixation device
Classification	Classification – II Product Code – MBI Classification name – Fastener, Fixation, Nondegradable, Soft Tissue Classification Rule – 888.3040 Device Panel – 87 - “Orthopedic surgery”
Predicate device(s)	Arthrex Inc., Retrobutton cleared under K062747
Indications for use	Tibial fixation of biological ligament during orthopaedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) reconstruction
Device description	ANCHORMAN is a PEEK cortical tibial suspensory fixation device, and functions via the looping of a biological or artificial tendon graft through the loop component of the device. The tendon graft is then pulled through the tibial and femoral tunnels. The wing components of the device rest on the tibial cortex, facilitating tensioning on the femoral side (if required). The device then provides tibial suspensory fixation, supporting the graft until aperture healing occurs and the graft integrates with the bone, at which point the device does not bear load and is redundant.

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Non-clinical testing	Comparative in-vitro testing on human cadaveric tibiae was performed and the results for ANCHORMAN were compared to that of the predicate. The results showed that ANCHORMAN possesses mechanical, chemical, physical and handling characteristics necessary to demonstrate that it is substantially equivalent to Retrobutton.
Clinical testing	Clinical data was not required to establish substantial equivalence between the ANCHORMAN and the predicate device.
Chemical differences	Although ANCHORMAN and the predicate are composed of different materials, and therefore have chemical differences, both PEEK (ANCHORMAN), UHMWPE and Titanium Ti6Al4V (RetroButton) are long established implant materials, with confirmatory biocompatibility testing verifying this. Comparative in-vitro testing on human cadaveric tibiae was performed and the results for ANCHORMAN were compared to that of the predicate, and showed that the chemical differences between ANCHORMAN and the predicate do not raise any new questions of safety and effectiveness
Physical differences	Although ANCHORMAN and the predicate have different designs and materials, direct comparative performance testing in cadaveric tibiae comparing ANCHORMAN and the predicate device has confirmed that, when the relevant performance/ clinical characteristics which may be affected by size (UTS, initial and cyclic displacement and stiffness) are equivalent with reference to the clinically identified failure levels.
Handling differences	Direct comparative performance testing in human cadaveric tibiae comparing ANCHORMAN and the predicate device has confirmed that, when implanted properly, the relevant performance/ clinical characteristics which may be affected by size (UTS, initial and cyclic displacement and stiffness) are equivalent with reference to the clinically identified failure levels. The cadaveric usability study for ANCHORMAN has demonstrated the appropriateness of this technique for users, even in worst case insertion and removal circumstances. These differences do not raise any new questions of safety and effectiveness
Substantial equivalence	Based on the similarities in design, function, indications for use and fundamental scientific technology, the devices that are the subject of this submission are similar to the predicate devices and do not introduce any new risks of safety or efficacy. Therefore, Summit Medical concludes that the subject device is substantially equivalent to the predicate device.