SECTION 5. 510(K) SUMMARY

AUG 3 1 2011

Submission Correspondent and Owner	Instratek, Inc. 4141 Directors Row, Suite H Houston, TX 77092 Phone: 281-890-8020 Fax: 281-890-8068 Email: jeff@instratek.com Contact: Mr. Jeff Seavey Vice President
Date summary prepared:	August 15, 2011
Device trade name:	CMC Cable FIX
Device common name:	Button/Suture
Device classification name:	Washer, Bolt Nut, HTN at 21 CFR 888.3030
Legally marketed device to which the device is substantially equivalent:	Arthrex Mini TightRope™ Repair Kit, K090107 Michelangelo Bunion System, K091763 (material only)
Description of the device:	The Instratek CMC Cable FIX is a suture button implant designed to stabilize the thumb metacarpal following removal or partial resection of the trapezium. The CMC Cable FIX is an adjunct in the healing process when used in conjunction with a biologic reconstruction of the ligament at the base of the thumb metacarpal for treatment of carpometacarpal (CMC) arthritis and instability. The implanted device consists of three (3) components: 1. Plate – 2-hole round – Ti-6Al-4v 2. Plate - 2-hole oblong w/break away guide wire – Ti-6AL-4v 3. #2 Suture – Ultra High Molecular Weight Polyethylene There are 3 accessories required to implant the device: 1. Cannulated Drill Bit – 17-4 Stainless Steel 2. K-wire - 316L Stainless Steel 3. Suture Passer - PTFE tubing

Intended use of the device:	The Instratek CMC Cable FIX is a suture button implant designed to stabilize the thumb metacarpal following removal or partial resection of the trapezium. The CMC Cable FIX is an adjunct in the healing process when used in conjunction with a biologic reconstruction of the ligament at the base of the thumb metacarpal for treatment of carpometacarpal (CMC) arthritis and instability.
Technological characteristics:	The technological characteristics between the predicate and proposed devices are the same.
Testing:	The following testing was performed to demonstrate substantial equivalence. • Comparative Suture Tensile Force (N) vs. Displacement (mm).
Conclusions:	There are no significant differences between the proposed and predicate device; therefore, the proposed device does not raise any questions regarding safety and effectiveness. The CMC Cable FIX, as designed, is as safe and effective as the predicate devices. Comparisons have been made to a legally marketed predicate device, and the device is determined to be substantially equivalent to the referenced predicate device currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Instratek, Inc.
% Mr. Jeff Seavey
4141 Director's Row
Suite H
Houston, Texas 77092

AUG 31 2011

Re: K111032
Trade/Device Name: Instratek CMC Cable FIX
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HTN
Dated: August 18, 2011
Received: August 18, 2011

Dear Mr. Seavey:

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.

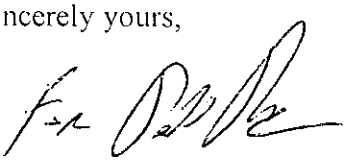
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number: K111032

Device Name: CMC Cable Fix

Indications for Use: The Instratek CMC Cable Fix is a suture button implant designed to stabilize the thumb metacarpal following removal or partial resection of the trapezium. The CMC Cable Fix is an adjunct in the healing process when used in conjunction with a biologic reconstruction of the ligament at the base of the thumb metacarpal for treatment of carpometacarpal (CMC) arthritis and instability.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111032