SECTION 5. 510(K) SUMMARY

Submission Correspondent and Owner:	Instratek, Inc. 4141 Directors Row, Suite H Houston, TX 77092 USA Phone: 281-890-8020 Fax: 281-890-8068 Email: jeff@instratek.com Contact: Mr. Jeff Seavey President
Date summary prepared:	July 9, 2013
Device trade name:	Instratek Jones-FX System
Device common name:	Bone Screw
Device classification name:	Screw, Fixation, Bone. HWC at 21 CFR Part 880.3040
Legally marketed device to which the device is substantially equivalent:	Arthrex, Low Profile Plate and Screw System, Cleared under K123241 Wright – 5th Metatarsal Fracture Screw, Cleared under K053136
Description of the device:	The Instratek Jones-FX System is comprised of screws in diameters 4.5mm, 5.5mm and 6.5mm. The screws are available in cannulated and non-cannulated versions and are constructed of TI-6AL-4V anodized titanium alloy conforming to ASTM F136. The screws have Torx heads. Instruments provided in the set include: • Tissue protector • K-wire guides • Drill guide inserts (3.1mm, 4.0mm and 4.9mm) • Tap Guide inserts (4.5mm, 5.5mm and 6.5mm) • K-wire (1.7mm x 230mm) • Cannulated drill bits (3.1mm, 4.0mm and 4.9mm) • Screw Taps, Cannulated (4.5mm, 5.5mm, 6.5mm) • Depth gauge • Driver blade • Fixed and Rachet Quick Connect Drivers • Countersink • Tray with Caddy

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Intended use of the device:	The Instratek 4.5mm, 5.5mm and 6.5mm screws are indicated for fixation of bone fractures, osteotomies, non-unions and mal-unions in bone reconstruction. These devices are not intended for use in the spine. The Instratek 4.5mm, 5.5mm, and 6.5mm screws are intended for the following surgical indications: • Metatarsal fractures • Fixation of malunions and nonunions • Acute fractures • Avulsion fractures • Repetitive stress fractures • Malleolar fractures • Talus fractures • Greater tuberosity fractures • Small joint fusion • Jones fractures • Osteotomies and non-unions in the foot and ankle
Technological characteristics:	The proposed device has the same technological characteristics as the predicate devices.
Testing:	No testing was conducted for inclusion with this submission.
Conclusions:	The results of the comparison of design, materials, intended use and technological characteristics demonstrate that the device is as safe and effective as the legally marketed predicate devices.

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

July 25, 2013

Instratek, Incorporated
% Mr. Jeff Seavey
President
4141 Directors Row, Suite H
Houston, Texas 77092

Re: K131620
Trade/Device Name: Instratek Jones-FX System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 20, 2013
Received: June 21, 2013

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 contact 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. 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,

Erin I. Keith

For

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

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number: K131620 (Page 1 of 1)

Device Name: Instratek Jones-FX System

Indications for Use:

The Instratek 4.5mm, 5.5mm, and 6.5mm screws are indicated for fixation of bone fractures, osteotomies, non-unions and mal-unions in bone reconstruction. These devices are not intended for use in the spine.

The Instratek 4.5mm, 5.5mm, and 6.5mm screws are intended for the following surgical indications:

- Metatarsal fractures
- Fixation of malunions and nonunions
- Acute fractures
- Avulsion fractures
- Repetitive stress fractures
- Malleolar fractures
- Talus fractures
- Greater tuberosity fractures
- Small joint fusion
- Jones fractures
- Osteotomies and non-unions in the foot and ankle

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)

Lori A. Wiggins

Division of Orthopedic Devices