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SECTION 5. 510(K) SUMMARY

Submission Correspondent and Owner	Instratek, Inc. 210 Springhill Drive Suite 130 Spring, TX 77386 DEC 0 8 2008 Phone: 281-890-8020 Fax: 281-890-8068 Email: jeff@instratek.com Contact: Mr. Jeff Seavey Vice President
Date summary prepared:	August 15, 2008
Device trade name:	HAV-Lok Bunion Correction System
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, K061925
Description of the device:	The HAV- Lok Kit is designed to assist in the reduction and control of increased pathologic intermetatarsal angles. HAV-Lok may eliminate the necessity of a traditional osteotomy in the correction of Hallux Valgus deformities within the indicated criteria. The implanted device consists of three (3) components: 1. Medial Oblong Plate 2. Lateral Oblong Plate 3. #3/4 Suture There are 4 accessories required to implant the device 1. Suture Lasso 2. K-wire 3. Cannulated Drill Bit 4. Drill Guide To achieve reduction of intermetatarsal angles, two suture paths are drilled through the first and second metatarsals. The oblong plates are positioned on the outside of the first and second metatarsals and the sutures are used to draw the plates together thereby reducing the intermetatarsal angle.

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Intended use of the device:	The Instratek HAV-Lok Bunion Correction System is intended for the following surgical indications: • To assist in the biomechanical reduction of abnormal intermetatarsal angle.
Technological characteristics:	The technological characteristics between the predicate and proposed devices are the same.
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 HAV-Lok Bunion Correction System, 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

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 8 2008

Instratek Inc.
% Mr. Jeff Seavey
210 Springhill Drive
Suite 130
Spring, Texas 77386

Re: K082384
Trade/Device Name: HAV-Lok Bunion Correction System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HTN
Dated: November 18, 2008
Received: November 18, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number: K082384 (pg 1/1)

Device Name: HAV-Lok Bunion Correction System

Indications for Use: The Instratek HAV-Lok Bunion Correction System is intended for the following surgical indications:

- To assist in the correction of Hallux Valgus deformities by providing reduction of the 1st intermetatarsal angle.

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)

Neil R. Ogden for M*m

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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