SECTION 5. 510(K) SUMMARY

MAY 17 2012

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 Vice President
Date summary prepared:	February 15, 2012
Device trade name:	Mini Cannulated Titanium Headed and Headless Screw Set
Device common name:	Bone Screw
Device classification name:	Screw, Fixation, Bone. HWC at 21 CFR Part 888.3040
Legally marketed device to which the device is substantially equivalent:	Osteomed K063298 Osteomed K010783 Koby Surgical K060026 BioPro K101030 Memometal K070039 Vilex K973309, K991197, K991151 Vilex K014154 Instratek K960537, K960533, K950704
Description of the device:	The Instratek Mini Cannulated Titanium Headed and Headless Screw Set is comprised of screws in diameters 2.5mm through 4.0mm. The screws are all cannulated and constructed of anodized titanium alloy. The screws have Torx heads. Instruments provided in the set include drivers (fixed and rotating) and blades, countersink/depth gauge, screw pickup, drill bits, threaded and unthreaded kwires and a caddy/tray.

Intended use of the device:	The Instratek Cannulated Titanium (Ti6AL4V) Headed & Headless Mini 2.5 mm, 3.0 mm and 4.0mm bone screws are indicated for use in the treatment of bone fractures, osteotomies, arthrodesis, osteochrondritis, and tendon reattachment in small bones and interfragmentary indications including specific long bone indications. The device is intended for, but not limited to, Hand Surgery, Orthopedic Surgery, Plastic Surgery and Podiatric Surgery. These devices are not intended for use in the spine. The Instratek Cannulated Titanium Headed & Headless Mini Screw Set is intended for the following surgical indications: • Scaphoid Fractures • Capitate • Metacarpal Fractures • Phalangeal Fractures • Ulnar Styloid Fractures • Small Joint Fusion • Humeral head Fractures • Intercarpal Fractures • Tarsal Fusions • Patellar Fractures • Interfragmentary Ulnar Fractures • Small Hand and Wrist Bone Fractures • Forefoot Interfragmentary Fractures • Lunate Fractures • Trapezial Fractures • Metatarsal Fractures • Radial Head Fractures • Osteo-Chondral • Ostero-Chondral Fractures • Glenoid Fractrures • Interphalangeal Fractures • Malleolar Fractures • Metaphyseal Fratures • Interfragmentary Radius Fractures • Distal Metatarsal Osteotomies • Midfoot Interfragmentary Fractures
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 Room –WO66-G609
Silver Spring, MD 20993-0002

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

MAY 17 2012

Re: K120493
Trade/Device Name: Mini Cannulated Titanium Headed and Headless Screw Set
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: February 15, 2012
Received: February 17, 2012

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: K120493

Device Name: Mini Cannulated Titanium Headed and Headless Screw Set

Indications for Use:

The Instratek Cannulated Titanium (Ti6AL4V) Headed & Headless Mini 2.5mm, 3.0mm and 4.0mm bone screws are indicated for use in the treatment of bone fractures, osteotomies, arthrodesis, osteochrondritis, and tendon reattachment in small bones and interfragmentary indications including specific long bone indications. The device is intended for, but not limited to, Hand Surgery, Orthopedic Surgery, Plastic Surgery and Podiatric Surgery. These devices are not intended for use in the spine.

The Instratek Cannulated Titanium Headed & Headless Mini Screw Set is intended for the following surgical indications:

- Scaphoid Fractures
- Capitate
- Metacarpal Fractures
- Phalangeal Fractures
- Ulnar Styloid Fractures
- Small Joint Fusion
- Humeral head Fractures
- Intercarpal Fractures
- Tarsal Fusions
- Patellar Fractures
- Interfragmentary Ulnar Fractures
- Small Hand and Wrist Bone Fractures
- Forefoot Interfragmentary Fractures
- Lunate Fractures
- Trapezial Fractures
- Metatarsal Fractures
- Radial Head Fractures
- Osteo-Chondral
- Ostero-Chondral Fractures
- Glenoid Fractrures
- Interphalangeal Fractures
- Malleolar Fractures
- Metaphyseal Fratures
- Interfragmentary Radius Fractures
- Distal Metatarsal Osteotomies
- Midfoot Interfragmentary Fractures

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 K120493