



KW0086 # 1/2

SEP - 9 2011

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**Internal Fixation Systems, Inc.  
510(k) Summary**

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**Company Name:** Internal Fixation Systems, Inc.  
10100 N.W. 116<sup>th</sup> Way, Suite 18  
Miami, Florida 33178

**Contact Name:** Christopher Endara  
10100 N.W. 116<sup>th</sup> Way, Suite 18  
Miami, Florida 33178  
(305) 884-5993

**Date Prepared:** August 12, 2011

**Trade Name:** IFS Bone Plates, Screws, and Washers

**Common Name:** Plate, Fixation, Bone  
Screw, Fixation, Bone  
Washer

**Classification:** 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories (HRS and NDG)  
21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener (HWC)

**Predicate Devices:**

- Arthrex Low Profile Plate and Screw System (K052614)
- Synthes Calcaneal Plate (K020401)
- GPC Medical Bone Plates and Screws (K092493)
- Synthes USA Modular Mini Fragment LCP System (K063049)
- Synthes USA 1.5 Mini Fragment LCP System (K090047)
- Synthes USA 2.4/2.7 Locking Foot Module (K071264)
- Depuy Orthopaedics Small Fragment Locking Plating System (K072083)
- Depuy Orthopaedics Small Bone Locking Plate System (K081546)
- Zimmer Inc. Universal Locking System 3.5mm Plates and Screws (K082527)
- Synthes Spherical Washers (K052483)

**Device Description:** IFS bone plates consists of various shapes as well as screws are intended to treat fractures and osteotomies of various bones, including the clavicle, pelvis, scapula, humerus, radius, ulna, femur, tibia, and fibula. The washers are to function with screws to prevent the screw head from breaking through the cortex of the bone by providing additional surface area during screw placement. The plates, screws, and washers are a one-piece device made of Titanium 6Al-4V ELI or stainless steel.

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Intended Use:	<p>IFS bone plates and screws, provided non-sterile, are intended to treat fractures and osteotomies of various bones including the clavicle, pelvis, scapula, humerus, radius, ulna, femur, tibia, calcaneus, and fibula.</p> <p>The IFS washers, provided non-sterile, are intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over an area when used for fracture fixation of small bones and bone fragments.</p>
Substantial Equivalence:	<p>IFS bone plates, screws, and washers have the same intended use, same technological characteristics, and materials as the predicate devices. Based on the information submitted, it is determined that the bone plate and screw system is substantially equivalent to the currently marketed predicate devices.</p>
Technological Characteristics Comparison:	<p>The IFS bone plates, screws, and washers are substantially equivalent to the predicate devices with respect to the design, function, and material. The plates have the same number of holes, similar thickness, lengths, widths, and material composition. The screws have the same diameters, lengths, and material composition. The washers have the same outer diameter, inner diameter, thickness, and material composition.</p>
Sterilization Information:	<p>The IFS Bone Plates, Screws, and Washers will be distributed non-sterile. The devices are sterilized by the end user per the AAMI Guidelines "Good Hospital Practice: Steam Sterilization and Sterility Assurance" and ANSI/AAMI/ISO 11737 guidelines to achieve the Sterility Assurance Level (SAL) of <math>10^{-6}</math>.</p>
Conclusion:	<p>There are no significant differences between the IFS bone plates, screws, and washers and the other implants as listed in the Substantially Equivalent Devices. The IFS plates, screws, and washers and the predicate devices have similar design attributes, material, and intended use thus is considered substantially equivalent.</p>



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

Internal Fixation Systems, Inc.  
% Mr. Christopher Endara  
10100 N.W. 116<sup>th</sup> Way, Suite 18  
Miami, Florida 33178

SEP - 9 2011

Re: K110086

Trade/Device Name: IFS Profile Plates, Screws, and Washers

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: HRS, HWC, NDG

Dated: August 19, 2011

Received: August 30, 2011

Dear Mr. Endara:

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

## Indications for Use

510(k) Number (if known): K110086

Device Name: IFS Bone Plates, Screws, and Washers

Indications for Use: IFS bone plates and screws, provided non-sterile, are intended to treat fractures and osteotomies of various bones including the clavicle, pelvis, scapula, humerus, radius, ulna, femur, tibia, calcaneus, and fibula.

The IFS washers, provided non-sterile, are intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over an area when used for fracture fixation of small bones and bone fragments.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

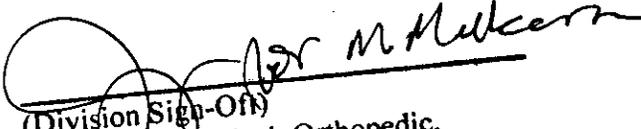
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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