



Food and Drug Administration
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In2bones SAS
% Norman Estrin, Ph.D.
Managing Partner
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9109 Copenhaver Drive
Potomac, Maryland 20854

June 10, 2016

Re: K160995

Trade/Device Name: NEOVIEW[®] Plating System

Regulation Number: 21 CFR 888.3030

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

Regulatory Class: Class II

Product Code: HRS

Dated: April 7, 2016

Received: April 11, 2016

Dear Dr. Estrin:

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 Parts 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 Industry and Consumer Education 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 Industry and Consumer Education 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 -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K160995

Device Name

NEOVIEW® Plating System

Indications for Use (Describe)

The NEOVIEW® Plating System is intended for fixation of intra-articular and extra-articular fractures of the distal radius and reconstruction of the distal radius.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
For In2Bones NEOVIEW® Plating System

Sponsor identification	In2Bones SAS 28 chemin du Petit Bois 69130 Ecully – France Phone: +33.4.72.29.26.26 Fax: +33.4.72.29.26.29
Establishment registration number	3010470577
Date of preparation	March 21st, 2016
Contact person	Norman F. Estrin, Ph.D. Estrin Consulting Group LLC 9109 Copenhaver Drive Potomac, MD 20854 Phone: (301) 279-2899 Cell: 240-994-9999 Email: estrin@yourFDAconsultant.com
Authorized Agent in the United States NEOVIEW® Plating System	Norman F. Estrin, Ph.D. Estrin Consulting Group LLC 9109 Copenhaver Drive Potomac, MD 20854 Phone: (301) 279-2899 Cell: 240-994-9999 Email: estrin@yourFDAconsultant.com
Proprietary Name	NEOVIEW® Plating System
Common name	NEOVIEW® Distal Radius Plate
Device classification regulation	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories Class II
Device Product Code and Panel	HRS: plate, fixation, bone 87 orthopedics

Device Description	<p>The NEOVIEW® Plating System is composed of the NEOVIEW® plates and the associated NEO screws.</p> <p>The NEOVIEW® plate is design to adequately maintain the bone fragments of distal radius and is made of PEEK, a material recognized for its mechanical and radiolucent properties.</p> <p>The fixation of NEOVIEW® plate to the bone is performed by the associated NEO screws that are available on locking or not locking versions.</p> <p><u>Sizes:</u> The NEOVIEW® plates include 4 different designs. The associated NEO screws are available in one diameter and a large range of lengths packaged individually of in a kit.</p> <p><u>Material:</u> The NEOVIEW® plates are made of PEEK according to standard ASTM F2026 and include a marker made of tantalum according to ASTM F560. The NEO screws are made of Titanium alloy Ti-6Al-4V according to ISO 5832-3 and ASTM F136.</p> <p><u>Single use:</u> The NEOVIEW® Plating System is designed for single use only.</p> <p><u>Sterilization:</u> The NEOVIEW® Plating System is supplied sterile, using gamma irradiation.</p> <p><u>Place of use:</u> The NEOVIEW® Plating System is indicated for use in a hospital, or outpatient surgery center where sterile field may be created and maintained.</p>
Predicate Devices	Piccolo Composite™ Distal Volar Radius Plate (K102597)
Indications for use:	<p>The NEOVIEW® Plating System is intended for fixation of intra-articular and extra-articular fractures of the distal radius and reconstruction of the distal radius.</p>

Comparison of the indications for use with the predicate devices:	The indications for use for the NEOVIEW® Plating System are similar to the predicate device Piccolo Composite™ Distal Volar Radius Plate (K102597) in intended use, design, material, technological characteristics and principles of operation.
Comparison of Technological characteristics and Substantial Equivalence Summary:	The NEOVIEW® Plating System is similar to the predicate device Piccolo Composite™ Distal Volar Radius Plate (K102597) in intended use, design, size ranges, principle of operation and materials.
Summary Performance Data	Performance testing of the NEOVIEW® Plating System was assessed through mechanical bench testing performed by an independent test laboratory, animal and clinical testing being considered not applicable. Testing performed included static and dynamic bending tests on NEOVIEW® Plating System. The results of the testing performed by the independent test laboratory indicate that the NEOVIEW® Plating System met the acceptance criteria.
CONCLUSION	Based on the comparison of indications for use and technological characteristics and the results of the testing performed, the NEOVIEW® Plating System is substantially equivalent to the predicate device identified in the 510(k) submission.