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G Special 510(k) SUMMARY

For the modification to Bioretec ActivaPin™ Product Group

MANUFACTURER

Bioretec Ltd.
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Contact person:
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Date prepared: December 19th, 2013

DEVICE NAME

Trade Name: Bioretec ActivaPin™

Bioretec ActivaPin™ Fusion

Bioretec ActivaNail™ Conical

Bioretec ActivaNail™ Flat

Bioretec ActivaPin™ HT

Common Name: Pin, Fixation

DEVICE CLASSIFICATION AND PRODUCT CODE

Device Classification Name: Pin, Fixation, Smooth

Classification Panel: Orthopedic

Regulation Number: 21 CFR 888.3040

Product Code: HTY

PREDICATE DEVICES

Bioretec ActivaPin™ (K061164), Bioretec ActivaPin™ Product Group (K080879)

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DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The modified ActivaPin™ Product Group is identical to the currently cleared device expect for the modification. The modification of the initial ActivaPin™ Product group 510(k) (K080879) adds one trade name; Bioretec ActivaPin™ HT in the ActivaPin™ Product Group. That device has a small modification to ActivaPin™ Fusion; the instrument accepting hole is made on the both ends instead of one end of the device to enable insertion in two directions. The labeling will be revised accordingly.

Bioretec ActivaPin™ Product Group covers Bioretec's bioabsorbable devices ActivaPin™, ActivaPin™ Fusion, ActivaPin™ HT, ActivaNail™ Conical and ActivaNail™ Flat.

The Bioretec ActivaPin™ products do not differ significantly or at all in purpose, design, materials, function or any other feature related to safety and effectiveness. ActivaPin™ HT is almost identical with a predicate device and the other devices of Bioretec's ActivaPin™ Product Group. ActivaPin™ HT is the same kind of device as ActivaPin™ Fusion, but it's both ends have an instrument accepting hole. The diameter of ActivaPin™ HT is 1.5 mm and the lengths are 20 - 70 mm.

The devices of Bioretec ActivaPin™ Product Group are indicated for fixation of bone fractures, osteotomies, arthrodeses and osteochondral fractures in the presence of appropriate immobilization.

The Bioretec ActivaPin™ Product Group devices are made of completely bioabsorbable poly(L-lactide-co-glycolide) (PLGA), and they degrade *in vivo* by hydrolysis into alpha-hydroxy acids that are metabolized by the body. As the operated bone fracture or osteotomy gains strength during healing, the Bioretec ActivaPin™ products gradually loses their strength, however, maintaining their function at least 8 weeks. Bioabsorption takes place within approximately two years thus eliminating the need for implant removal surgery.

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EQUIVALENCE TO MARKETED PRODUCTS

The devices of modified Bioretec ActivaPin™ Product Group are substantially equivalent to the previously cleared Bioretec ActivaPin™ (K061164) and Bioretec ActivaPin™ Product Group (K080879).

The modified Bioretec ActivaPin™ products have the same intended use and principles of operation, and also the same technological characteristic and performance as the previously cleared Bioretec ActivaPin™ (K061164) and Bioretec ActivaPin™ Product Group (K080879). Any differences between modified Bioretec ActivaPin™ products and predicate device do not raise any questions of safety and effectiveness.

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

January 22, 2014

Bioretec Limited
Ms. Minna Räsänen
Quality and Regulatory Affairs Manager
Hermiankatu 22, Modulight Building
FI-33720 Tampere
Finland

Re: K133950
Trade/Device Name: ActivaPin™ Product Group (ActivaPin™, ActivaPin™ Fusion, ActivaNail™ Conical, ActivaNail™ Flat, ActivaPin™ HT)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: December 19, 2013
Received: December 23, 2013

Dear Ms. Räsänen:

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" (21 CFR 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,

Ronald P. Jean -S for

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

Enclosure

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F Indications for Use Statement

Submitter: Bioretec Ltd.

510(k) Number: K133950

Device Name: **ActivaPin™ Product Group**

ActivaPin™

ActivaPin™ Fusion

ActivaNail™ Conical

ActivaNail™ Flat

ActivaPin™ HT

Indications for Use:

The devices of **Bioretec ActivaPin™ Product Group** including ActivaPin™, ActivaPin™ Fusion, ActivaNail™ Conical, ActivaNail™ Flat and ActivaPin™ HT are indicated for fixation of bone fractures, osteotomies, arthrodeses and osteochondral fractures in the presence of appropriate immobilization.

Contraindications:

1. High-load bearing applications
2. Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient's co-operation cannot be guaranteed.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Frank -S

Division of Orthopedic Devices