



JAN 22 2014

G Special 510(k) SUMMARY

For the modification to Bioretec ActivaPin™ Product Group

MANUFACTURER

Bioretec Ltd.
Hermiankatu 22, Modulight Building
FI-33720 Tampere
FINLAND

Contact person:

Ms. Minna Räsänen
Quality and Regulatory Affairs Manager
Direct: +358 20 778 9509
Mobile: +358 40 868 1606
Fax: +358 3 317 0225
E-mail: Minna.Rasanen@bioretec.com

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)



DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The modified ActivaPin™ Product Group is identical to the currently cleared device except 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.



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

Page 2 – Ms. Minna Räsänen

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



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

Page __ of __

Elizabeth Frank -S

Division of Orthopedic Devices



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

Biorettec 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:

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Page 2 – Ms. Minna Räsänen

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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

Page 3 – Ms. Minna Räsänen

Concurrence & Template History Page

[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K133950

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197.415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197.415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Tara Shepherd
Branch Chief Sign-Off	Elizabeth L. Kunkoski
Division Sign-Off	Ronald P. Jean -S 2014.01.22 13:30:51 -05'00'

f/t:TNS:rj:1/22/14

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1 st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".
4/2/2013	M. McCabe Janicki	Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)..." Replaced broken Compliance link with general link to DSMICA.
4/12/2013	Margaret McCabe Janicki	Fixed a typo: Paragraph 1, final sentence, "We remind you, however; that device labeling must be truthful..." Replaced incorrect semicolon with a comma.



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

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

Page ___ of ___

Elizabeth Frank -S

Division of Orthopedic Devices



C 510(k) Cover Letter

FDA CDRH DMC

DEC 23 2013

Received

Food and Drug Administration *
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

K133950

Dear Receiver,

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, 21 CFR 807.81(a)(3) and the FDA guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device", Bioretec Ltd. ("Company") is submitting the attached premarket notification for its ActivaPin™ Product group. This premarket notification is Special 510(k): Device Modification for ActivaPin™ Product group to add a modified implant and revising labeling accordingly. This is the only modification to the initial 510(k) K080879 to be cleared. The change does not affect the intended use or alter the fundamental scientific technology of the device. The submission is attached as two copies, one of which is a paper copy and one is an eCopy as required in the FDA Guidance document issued on December 31, 2012 "eCopy Program for Medical Device Submissions". The eCopy is an exact duplicate of the paper copy.

The Bioretec's ActivaPin™ Product group common name is Pin, Fixation. The submission K080879 covered Bioretec ActivaPin™ Product Group including bioabsorbable devices ActivaPin™, ActivaPin™ Fusion, ActivaNail™ Conical and ActivaNail™ Flat. The submission included devices of 1.5 mm, 2.0 mm, 2.7 mm and 3.2 mm diameters with lengths from 5 to 70 mm, and the custom instruments used to implant the devices.

To conform with the FDA's August 12, 2005, Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)'s, the following information concerning the design and use of ActivaPin™ Product group is provided:

A handwritten signature in black ink, appearing to be "Uz", is located at the bottom right of the page.



Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	-	-
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

As explained in more detail in the attached Special 510(k) notice, the addition to ActivaPin™ Product group, ActivaPin™ HT is substantially equivalent to previously cleared ActivaPin™ (K061164) and ActivaPin™ Product Group (K080879).

In accordance with the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Bioretec Ltd. has submitted the required application fee of (b)(4). A copy of the User Fee Cover Sheet is provided with the attached premarket notification.

Bioretec Ltd. considers its intent to market the ActivaPin™ HT as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employers, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company therefore requests that FDA not disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore not disclosable under the Freedom of Information Act even after the existence of this application becomes public. We ask that you consult with the Company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

We trust that the information provided in the Special 510(k) notice is sufficient for FDA to find the modified ActivaPin™ Product group substantially equivalent to its predicate devices for



the listed indication. If you have any additional questions regarding the Special 510(k) notice, please contact me at the number below. Upon clearance of the device, please fax the substantial equivalence letter to me at +358 3 317 0225 and e-mail it to my e-mail address Minna.Rasanen@bioretec.com and the cc e-mail address Minna.Veiranto@bioretec.com .

Sincerely,

A handwritten signature in blue ink, appearing to be "Minna Räsänen", written over a horizontal line.

Minna Räsänen

Quality and Regulatory Affairs Manager

Direct: +358 20 778 9509
Mobile: +358 40 868 1606
Fax: +358 3 317 0225
E-mail: Minna.Rasanen@bioretec.com

Minna Veiranto

R&D Manager

Email: Minna.Veiranto@bioretec.com



A Medical Device User Fee Cover Sheet (Form FDA 3601)

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) BIORETEC LTD Hermiankatu 22, Modulight Building Tampere Finland FI-33720 FI 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2. CONTACT NAME Minna Rasanen 2.1 E-MAIL ADDRESS minna.rasanen@bioretec.com 2.2 TELEPHONE NUMBER (include Area code) +358-408681606 2.3 FACSIMILE (FAX) NUMBER (include Area code)	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm) Select an application type:		
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)		

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.	
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population
<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]	
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4) 19-Dec-2013	

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)



B CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET		Form Approval OMB No. 0910-0120 Expiration Date: December 31, 2013 See PRA Statement on page 5.		
Date of Submission December 19th, 2013	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)		
SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Request for Feedback <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)				
SECTION B SUBMITTER, APPLICANT OR SPONSOR				
Company / Institution Name Bioretec Ltd.		Establishment Registration Number (if known)		
Division Name (if applicable)		Phone Number (including area code) (+358) 20 778 9500		
Street Address Hermiankatu 22, Modulight Building		FAX Number (including area code) (+358) 3 317 0225		
City Tampere	State / Province	ZIP/Postal Code FI-33720	Country Finland	
Contact Name Ms. Minna Räsänen (Ms. Minna Veiranto)				
Contact Title Q&RA Manager / R&D Manager		Contact E-mail Address minna.rasanen@bioretec.com / minna.veiranto@bioretec.com		
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)				
Company / Institution Name				
Division Name (if applicable)		Phone Number (including area code)		
Street Address		FAX Number (including area code)		
City	State / Province	ZIP Code	Country	
Contact Name				
Contact Title		Contact E-mail Address		

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (<i>specify</i>):					
SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Other Reason (<i>specify</i>):					
SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input checked="" type="checkbox"/> Other Reason (<i>specify</i>): Device modification that does not affect the intended use or alter the fundamental scientific technology of the device.					

SECTION E								ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS									
Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information									
1	HTY	2		3		4		<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement									
5		6		7		8											
Information on devices to which substantial equivalence is claimed (if known)																	
<i>510(k) Number</i>		<i>Trade or Proprietary or Model Name</i>				<i>Manufacturer</i>											
1	K080879	1	ActivaPin™				1	Bioretec Ltd.									
2	K061164	2	ActivaPin™				2	Bioretec Ltd.									
3		3					3										
4		4					4										
5		5					5										
6		6					6										
SECTION F										PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS							
Common or usual name or classification name																	
Pin, fixation																	
Trade or Proprietary or Model Name for This Device							Model Number										
1	ActivaPin™ HT						1	See Product Reference Codes in Special 510(k) submissio									
2	FUSE LINK (private labeled for FOOTMIND, INC.)						2	chapter M (Table M-1)									
3							3										
4							4										
5							5										
FDA document numbers of all prior related submissions (regardless of outcome)																	
1	2	3	4	5	6	7	8	9	10	11	12						
Data Included in Submission																	
<input type="checkbox"/> Laboratory Testing <input type="checkbox"/> Animal Trials <input type="checkbox"/> Human Trials																	
SECTION G														PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS			
Product Code		C.F.R. Section (if applicable)						Device Class									
888.3040		21 CFR 888.3040						<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified									
Classification Panel																	
Indications (from labeling)																	

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Bioretec Ltd.		Establishment Registration Number		
Division Name (if applicable)		Phone Number (including area code) (+358) 20 778 9500		
Street Address Hermiankatu 22, Moduligth Building		FAX Number (including area code) (+358) 3 317 0225		
City Tampere		State / Province	ZIP Code FI-33720	Country Finland
Contact Name Ms. Minna Räsänen	Contact Title Q&RA Manager		Contact E-mail Address minna.rasanen@bioretec.com	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name (if applicable)		Phone Number (including area code)		
Street Address		FAX Number (including area code)		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name (if applicable)		Phone Number (including area code)		
Street Address		FAX Number (including area code)		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS					
Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
1	Standards No.	Standards Organization FDA	Standards Title Guidance Document for Testing Biodegradable Polymer Implant Devices	Version Draft	Date 04/20/1996
2	Standards No.	Standards Organization FDA	Standards Title Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA	Version Second edition	Date 08/30/2002
3	Standards No.	Standards Organization ANSI/AAMI/ISO 14971:2007	Standards Title Medical devices - Application of risk management to medical devicesTest	Version Second edition	Date 3/1/2007
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date
Please include any additional standards to be cited on a separate page.					
<p>This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> <p style="text-align: center;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>					



C 510(k) Cover Letter

Food and Drug Administration *
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Receiver,

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, 21 CFR 807.81(a)(3) and the FDA guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device", Bioretec Ltd. ("Company") is submitting the attached premarket notification for its ActivaPin™ Product group. This premarket notification is Special 510(k): Device Modification for ActivaPin™ Product group to add a modified implant and revising labeling accordingly. This is the only modification to the initial 510(k) K080879 to be cleared. The change does not affect the intended use or alter the fundamental scientific technology of the device. The submission is attached as two copies, one of which is a paper copy and one is an eCopy as required in the FDA Guidance document issued on December 31, 2012 "eCopy Program for Medical Device Submissions". The eCopy is an exact duplicate of the paper copy.

The Bioretec's ActivaPin™ Product group common name is Pin, Fixation. The submission K080879 covered Bioretec ActivaPin™ Product Group including bioabsorbable devices ActivaPin™, ActivaPin™ Fusion, ActivaNail™ Conical and ActivaNail™ Flat. The submission included devices of 1.5 mm, 2.0 mm, 2.7 mm and 3.2 mm diameters with lengths from 5 to 70 mm, and the custom instruments used to implant the devices.

To conform with the FDA's August 12, 2005, Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)'s, the following information concerning the design and use of ActivaPin™ Product group is provided:



Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	-	-
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

As explained in more detail in the attached Special 510(k) notice, the addition to ActivaPin™ Product group, ActivaPin™ HT is substantially equivalent to previously cleared ActivaPin™ (K061164) and ActivaPin™ Product Group (K080879).

In accordance with the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Bioretec Ltd. has submitted the required application fee of (b)(4). A copy of the User Fee Cover Sheet is provided with the attached premarket notification.

Bioretec Ltd. considers its intent to market the ActivaPin™ HT as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company therefore requests that FDA not disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore not disclosable under the Freedom of Information Act even after the existence of this application becomes public. We ask that you consult with the Company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

We trust that the information provided in the Special 510(k) notice is sufficient for FDA to find the modified ActivaPin™ Product group substantially equivalent to its predicate devices for



the listed indication. If you have any additional questions regarding the Special 510(k) notice, please contact me at the number below. Upon clearance of the device, please fax the substantial equivalence letter to me at +358 3 317 0225 and e-mail it to my e-mail address Minna.Rasanen@bioretec.com and the cc e-mail address Minna.Veiranto@bioretec.com .

Sincerely,

A handwritten signature in blue ink, appearing to read "Minna Räsänen", with a long horizontal flourish extending to the right.

Minna Räsänen

Quality and Regulatory Affairs Manager

Direct: +358 20 778 9509

Mobile: +358 40 868 1606

Fax: +358 3 317 0225

E-mail: Minna.Rasanen@bioretec.com

Minna Veiranto

R&D Manager

Email: Minna.Veiranto@bioretec.com



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E Screening Checklist

Item	Present	Inadequate	N/A
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CDRH Premarket Review Submission Cover Sheet	B-1		
510(k) Cover Letter	C-1		
Cover letter, containing the elements listed on "Content of 510(k)" at Device Advice.	C-1 D-1		
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Class III Summary and Certification			I-1
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F Indications for Use Statement

Submitter: Bioretec Ltd.

510(k) Number:

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

Page ___ of ___



G Special 510(k) SUMMARY

For the modification to Bioretec ActivaPin™ Product Group

MANUFACTURER

Bioretec Ltd.
Hermiankatu 22, Modulight Building
FI-33720 Tampere
FINLAND

Contact person:

Ms. Minna Räsänen
Quality and Regulatory Affairs Manager
Direct: +358 20 778 9509
Mobile: +358 40 868 1606
Fax: +358 3 317 0225
E-mail: Minna.Rasanen@bioretec.com

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)



DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The modified ActivaPin™ Product Group is identical to the currently cleared device except 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.



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.



H Truthful and Accuracy Statement

I certify that, in my capacity as Chief Executive Officer of Bioretec Ltd., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

A handwritten signature in blue ink, appearing to read "Simo Hietaniemi", is written over a horizontal line.

Simo Hietaniemi

December 19th, 2013

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].



I Class III Summary and Certification (N.A.)

This section does not apply.

J Financial Certification or Disclosure Statement (N.A.)

This section does not apply.

K Declarations of Conformity and Summary Reports

1 CONCISE SUMMARY OF DESIGN CONTROL ACTIVITIES

Risk assessment is performed according to ANSI/AAMI/ISO 14971:2000. FMEA technique is applied. See table below for the verification tests and acceptance criteria.

Table K-1. Verification tests and acceptance criteria.

Modification	Test Performed	Acceptance Criteria
The ActivaPin™ HT can be inserted in two directions.	(b)(4)	(b)(4)

In the risk assessment the probability of the risk was assessed negligible.

According to risk assessment the residual risk is acceptable. The residual risk of each hazard was estimated based on the probability and severity of occurrence.



2 DECLARATION OF CONFORMITY

To the best of my knowledge, the verification and validation activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

 19.12.2013 (date and signature)

Minna Räsänen

Quality Manager, Bioretec Ltd.

The manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

 19.12.2013 (date and signature)

Simo Hietaniemi

Chief Executive Officer, Bioretec Ltd.



L Executive Summary

1 DEVICE DESCRIPTION

Bioretec ActivaPin™ Product Group covers Bioretec's bioabsorbable devices ActivaPin™, ActivaPin™ Fusion, ActivaNail™ Conical, ActivaNail™ Flat and ActivaPin™ HT. They are same generic type and do not differ significantly or at all in purpose, design, materials, function or any other feature related to safety and effectiveness. Only differences between original ActivaPin™ and its modifications are the design change of the distal or proximal head of the implant, and the change in labeling.

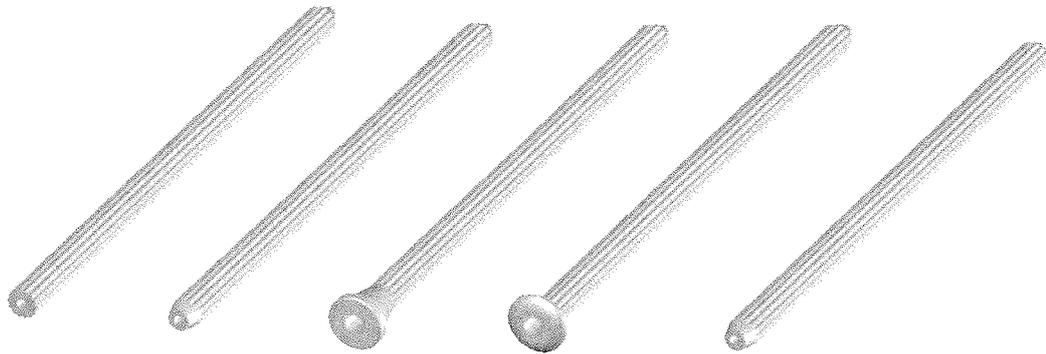


Figure L-1: Designs of Bioretec ActivaPin™ Product Group's devices

The ActivaPin™ HT is almost identical to the predicate device with modification of the both ends that are tapered and have a small hole for accepting the insertion instrument, identical to ActivaPin™ Fusion proximal end.

The Bioretec ActivaPin™ products are made of completely bioabsorbable poly(L-lactide-co-glycolide) (85L/15G). This material is designed to maintain its mechanical functionality during the bone healing and to allow complete resorption of the implant after healing has taken place, thus eliminating the need for implant removal surgery.

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.

Surgical operation techniques are similar to methods used with Bioretec ActivaPin™ (K061164) and Bioretec ActivaPin™ Product Group (K080879). After the proper exposure and reduction using standard surgical procedure, the devices of Bioretec ActivaPin™ Product Group are inserted into the suitable drill hole through the fracture/osteotomy plane. The



devices of Bioretec ActivaPin™ Product Group are designed to be used with customized instrumentation.

The Bioretec ActivaPin™ products are sterilized with gamma irradiation and packed into polystyrene-polypropylene holder, which enables aseptic placement during operation. The devices in their holder are packed into an aluminum foil pouch to maintain sterility and create a moisture barrier. The aluminum foil pouch maintains the integrity of package throughout the shelf life. The sealed aluminum laminate pouch is protected against physical impact by a cardboard shelf box.

2 DEVICE COMPARISON TABLE

Table L-1: Device comparison between the devices of Bioretec ActivaPin™ Product Group and predicate device:

Feature For Comparison	Bioretec ActivaPin™ (K061164)	Bioretec ActivaPin™ Product Group (K080879)	Bioretec ActivaPin™ HT
Device Classification Name	Pin, Fixation, Smooth	Pin, Fixation, Smooth	Pin, Fixation, Smooth
Device Common name	Pin, Fixation	Pin, Fixation	Pin, Fixation
Intended use	Properly used, in the presence of adequate immobilization, the ActivaPin™ maintains accurate alignment of bone fractures, apical fragments and osteochondral fragments after surgical procedure.	Properly used, in the presence of adequate immobilization, the ActivaPin™ Product Group maintains accurate alignment of bone fractures, apical fragments and osteochondral fragments after surgical procedure.	Properly used, in the presence of adequate immobilization, the ActivaPin™ HT maintains accurate alignment of bone fractures, apical fragments and osteochondral fragments after surgical procedure.
Indication	Indicated for fixation of bone fractures, osteotomies, arthrodeses and osteochondral fractures in the presence of appropriate immobilization.	Indicated for fixation of bone fractures, osteotomies, arthrodeses and osteochondral fractures in the presence of appropriate immobilization.	Indicated for fixation of bone fractures, osteotomies, arthrodeses and osteochondral fractures in the presence of appropriate immobilization.
Special patient population	The effect of the ActivaPin™ upon the healing of growth plate has not been tested clinically.	The effect of the ActivaPin™ Product Group upon the healing of growth plate has not been tested clinically.	The effect of the ActivaPin™ HT upon the healing of growth plate has not been tested clinically.
Where used (hospital, home, ambulance, etc.)	Prescription Device; Federal law (USA) restricts this device to sale by or on the order of a licensed physician.	Prescription Device; Federal law (USA) restricts this device to sale by or on the order of a licensed physician.	Prescription Device; Federal law (USA) restricts this device to sale by or on the order of a licensed physician.
Human factors	The surgeon should be familiar with the devices, the method of application and the surgical procedure prior to performing the surgery.	The surgeon should be familiar with the devices, the method of application and the surgical procedure prior to performing the surgery.	The surgeon should be familiar with the devices, the method of application and the surgical procedure prior to performing the surgery.
Design	Grooved Pin with tapered distal end.	Grooved Pin with design modifications on the proximal end (tapering, head).	Grooved Pin with tapered distal and proximal ends with hole for the instrument.



Performance	Mechanical performance is described in ActivaPin™ 510 (k) K061164.	Mechanical and biomechanical performance is the same as that of Bioretec ActivaPin™ (K061164).	Mechanical performance is demonstrated in K061164 and K080879.
Standards met	The Recognized Consensus Standards for devices with product code HTY are not applicable for Bioabsorbable polymer implants. See section W for standards applied.	The Recognized Consensus Standards for devices with product code HTY are not applicable for Bioabsorbable polymer implants. See section W for standards applied.	The Recognized Consensus Standards for devices with product code HTY are not applicable for Bioabsorbable polymer implants. See section W for standards applied.
Materials	Poly(L-lactide-co-glycolide) (85L/15G)	Poly(L-lactide-co-glycolide) (85L/15G)	Poly(L-lactide-co-glycolide) (85L/15G)
Dimensions	Diameter: 1.5-3.2mm; Length: 20-70mm	Diameter: 1.5-3.2mm; Length: 20-70mm	Diameter: 1.5mm; Length: 20-70mm
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Pyrogenicity	Pyrogen free	Pyrogen free	Pyrogen free
Instrumentation	Custom Instruments	Custom Instruments	Custom Instruments
Sterility	(b)(4)		



3 CONCISE SUMMARY OF PERFORMANCE TESTING

The mechanical properties are identical to predicate devices as there are no changes in the design that would affect the mechanical performance.

4 SUBSTANTIAL EQUIVALENCE ACCORDING TO PERFORMANCE TESTING

The only change to be cleared in this Special 510(k) submission is modification of the ActivaPin™ Product Group by adding one device in it. The modification is minimal and almost identical to the other devices in the ActivaPin™ Product Group. The only changes are the addition of the instrument accepting hole in the distal tip of the device and revising labeling accordingly. The change does not affect the intended use or alter the fundamental scientific technology of the device

The basic principles of surgical technique are not changed. Therefore the adding a new device in the ActivaPin™ Product Group do not raise any new questions of safety and effectiveness. ActivaPin™ HT is substantially equivalent to its claimed predicate devices ActivaPin™ (K061164) and Bioretec ActivaPin™ Product Group (K080879).



M Device Description

1 MATERIAL

The ActivaPin™ Product Group material has not been changed. It is a resorbable fixation pin constructed of uniaxially oriented, bioabsorbable Poly-L-lactide-co-glycolide (b)(4)

(b)(4) The polymers in the ActivaPin™ Product Group 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 ActivaPin™ Product Group gradually loses its strength, however, maintaining its function at least 8 weeks. Bioabsorption takes place within two years, thus eliminating the need for implant removal surgery.

2 INDICATIONS

The ActivaPin™ Product Group indications have not been changed. The devices of the Bioretec ActivaPin™ Product Group are indicated for fixation of bone fractures, osteotomies, arthrodeses and osteochondral fractures in the presence of appropriate immobilization.

3 CONTRAINDICATIONS

The contraindications for the ActivaPin™ Product Group have not been changed. The ActivaPin™ Product Group is contraindicated in:

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.

4 SPECIFICATIONS

There has not been that kind of changes in ActivaPin™ Product Group specifications that would have been submitted to FDA based on the FDA guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device". Pins are offered in several different dimensions, including diameters from 1.5 mm to 3.2 mm and lengths from 20 mm to 70 mm, dimensions that are bracketed by the diameters and lengths of the predicate devices.

5 PRODUCT DESCRIPTION TABLE

The product description table for the ActivaPin™ Product Group has the following addition:



Table M-1: Product Description Table of ActivaPin™ HT

Product Description	Product Reference Code	Diameter	Length
ActivaPin™ HT 1.5 mm x 20 mm	B-APHT-1520	1.5 mm	20 mm
ActivaPin™ HT 1.5 mm x 30 mm	B-APHT-1530	1.5 mm	30 mm
ActivaPin™ HT 1.5 mm x 40 mm	B-APHT-1540	1.5 mm	40 mm
ActivaPin™ HT 1.5 mm x 50 mm	B-APHT-1550	1.5 mm	50 mm
ActivaPin™ HT 1.5 mm x 60 mm	B-APHT-1560	1.5 mm	60 mm
ActivaPin™ HT 1.5 mm x 70 mm	B-APHT-1570	1.5 mm	70 mm
FUSE LINK 1.5 mm x 30 mm	FFP-1530	1.5 mm	30 mm

Please note that ActivaPin™ HT will be private labeled for distribution in the USA as FUSE LINK. Footmind Inc. will also assemble a convenience kit, (b)(4) where there are legally marketed components: ActivaPin™ HT private labeled as FUSE LINK, Applicator with K-Wire Ø1.6 mm, disposable, for 1.5 mm pins, private labeled as FUSE LINK Disposable applicator (K071863) and (b)(4)

The technical drawing for the ActivaPin™ HT is included in Appendix 1.

6 INSTRUMENT DESCRIPTION TABLE

ActivaPin™ Product Group instrument description table has not been changed. Please note that Disposable Pin Applicator with K-wire for 1.5 mm ActivaPin (K071863) will be private labeled for distribution in the USA as FUSE LINK Disposable applicator and included in a convenience kit with the FUSE LINK and (b)(4)

7 PRINCIPLES OF OPERATION

The ActivaPin™ Product Group basic principles of operation have not been changed. Please find as an Appendix 2 the surgical technique for ActivaPin™ HT and as Appendix 3 the FUSE LINK Surgical Technique with FUSE LINK Disposable applicator and (b)(4)



N Substantial Equivalence Discussion

The ActivaPin™ HT Bioabsorbable Pin with its reusable custom instrumentation or Disposable Pin Applicator with K-wire instrument set is substantially equivalent to the predicate ActivaPin™ Bioabsorbable Pin with its reusable custom instrumentation (K061164) and ActivaPin™ Product Group (K080879). The only modification to be cleared with FDA is the adding a tapering and an instrument accepting hole in the both ends of the implant and the labeling change accordingly. The change does not affect the intended use or alter the fundamental scientific technology of the device.

1 PREDICATE DEVICES

Device comparison information between previously cleared and modified ActivaPin™ and ActivaPin™ Product Group is presented in the concise summary table N-1 below.

Table N-1: Predicate devices

Feature For Comparison	Bioretec ActivaPin™	Bioretec ActivaPin™ Product Group	Bioretec ActivaPin™ HT
Device Classification Name	Pin, Fixation, Smooth	Pin, Fixation, Smooth	Pin, Fixation, Smooth
Device Common name	Pin, Fixation	Pin, Fixation	Pin, Fixation
Intended use	Properly used, in the presence of adequate immobilization, the ActivaPin™ maintains accurate alignment of bone fractures, apical fragments and osteochondral fragments after surgical procedure.	Properly used, in the presence of adequate immobilization, the ActivaPin™ Fusion maintains accurate alignment of bone fractures, apical fragments and osteochondral fragments after surgical procedure.	Properly used, in the presence of adequate immobilization, the ActivaPin™ HT maintains accurate alignment of bone fractures, apical fragments and osteochondral fragments after surgical procedure.
Indication	Indicated for fixation of bone fractures, osteotomies, arthrodeses and osteochondral fractures in the presence of appropriate immobilization.	Indicated for fixation of bone fractures, osteotomies, arthrodeses and osteochondral fractures in the presence of appropriate immobilization.	Indicated for fixation of bone fractures, osteotomies, arthrodeses and osteochondral fractures in the presence of appropriate immobilization.
Special patient population	The effect of the ActivaPin™ upon the healing of growth plate has not been tested clinically.	The effect of the ActivaPin™ Product Group upon the healing of growth plate has not been tested clinically.	The effect of the ActivaPin™ HT upon the healing of growth plate has not been tested clinically.
Where used (hospital, home, ambulance, etc.)	Prescription Device; Federal law (USA) restricts this device to sale by or on the order of a licensed physician.	Prescription Device; Federal law (USA) restricts this device to sale by or on the order of a licensed physician.	Prescription Device; Federal law (USA) restricts this device to sale by or on the order of a licensed physician.
Human factors	The surgeon should be familiar with the devices, the method of application and the surgical procedure prior to performing the surgery.	The surgeon should be familiar with the devices, the method of application and the surgical procedure prior to performing the surgery.	The surgeon should be familiar with the devices, the method of application and the surgical procedure prior to performing the surgery.



Design	Grooved Pin with tapered distal end.	Grooved Pin with design modifications on the distal and proximal ends (tapering, head).	Grooved Pin with tapered distal and proximal ends with hole for instrument.
Performance	Mechanical performance is described in ActivaPin™ 510 (k) K061164.	Mechanical and biomechanical performance is the same as that of Bioretec ActivaPin™ (K061164).	Mechanical performance is demonstrated in K061164 and K080879.
Standards met	The Recognized Consensus Standards for devices with product code HTY are not applicable for Bioabsorbable polymer implants. See section W for standards applied.	The Recognized Consensus Standards for devices with product code HTY are not applicable for Bioabsorbable polymer implants. See section W for standards applied.	The Recognized Consensus Standards for devices with product code HTY are not applicable for Bioabsorbable polymer implants. See section W for standards applied.
Materials	Poly(L-lactide-co-glycolide) (85L/15G)	Poly(L-lactide-co-glycolide) (85L/15G)	Poly(L-lactide-co-glycolide) (85L/15G)
Dimensions	Diameter: 1.5-3.2mm; Length: 20-70mm	Diameter: 1.5-3.2mm; Length: 20-70mm	Diameter: 1.5mm; Length: 20-70mm
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Pyrogenicity	Pyrogen free	Pyrogen free	Pyrogen free
Instrumentation	Custom Instruments	Custom Instruments	Custom Instruments
Sterility	Sterilized with Gamma irradiation	Sterilized with Gamma irradiation	Sterilized with Gamma irradiation

2 INTENDED USE

The ActivaPin™ Product Group intended use and indications have not been changed. The modification described in this Special 510(k) change does not affect the intended use of the device. ActivaPin™ HT is indicated for fixation of bone fractures, osteotomies, arthrodeses and osteochondral fractures in the presence of appropriate immobilization.

3 TECHNOLOGICAL CHARACTERISTICS

The ActivaPin™ Product Group technological characteristics have not been changed. The modification described in this Special 510(k) change does not alter the fundamental scientific technology of the device.

3.1 Material

The ActivaPin™ Product Group material has not been changed. The Bioretec ActivaPin™ HT is made of Poly(L-lactide-co-glycolide) -copolymer consisting of 85% of L-lactide and 15% of glycolide.



3.2 Manufacturing Method

The ActivaPin™ Product Group manufacturing method has not been changed. The Bioretec

(b)(4)

3.3 Strength Loss and Bioresorption Time

The ActivaPin™ Product Group strength loss and bioresorption times have not been changed.

The Bioretec ActivaPin™ HT gradually loses its strength, however, maintaining strength and function for at least 8 weeks. Complete bioabsorption takes place within two years.

3.4 Mechanical Properties

The mechanical properties of the ActivaPin™ Product Group have not been changed.

3.5 Design of the Implant

The ActivaPin™ HT design is a modification to the design of the predicate device ActivaPin™. The different configurations in the ActivaPin™ Product Group can be seen in the Figure M-1. The modification of ActivaPin™ HT is tapering the both ends of the device and adding an instrument accepting hole in the both ends identical to the hole in the one end of ActivaPin™ Fusion in the previously cleared ActivaPin™ Product Group.

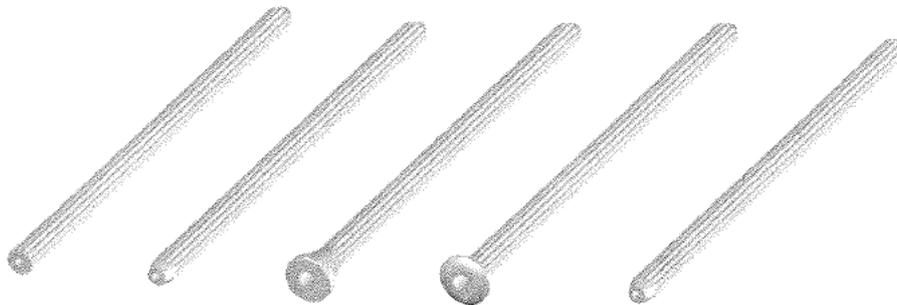


Figure M-1: Designs of Bioretec ActivaPin™ Product Group's devices

4 PRINCIPLES OF OPERATION

The ActivaPin™ Product Group basic principles of operation have not been changed.



5 SUBSTANTIAL EQUIVALENCE DISCUSSION SUMMARY

The only change to be cleared in this Special 510(k) submission is modification of the ActivaPin™ Product Group by adding one device in it. The modification is minimal and almost identical to the other devices in the ActivaPin™ Product Group. The only changes are the addition of the instrument accepting hole in the distal tip of the device and revising labeling accordingly. The change does not affect the intended use or alter the fundamental scientific technology of the device.

The basic principles of surgical technique are not changed. Therefore the adding a new device in the ActivaPin™ Product Group and labeling accordingly do not raise any new questions of safety and effectiveness. ActivaPin™ HT is substantially equivalent to its claimed predicate devices ActivaPin™ (K061164) and Bioretec ActivaPin™ Product Group (K080879).



O Proposed Labeling

Appendices of this premarket notification below include copies of final draft of proposed labeling for the **ActivaPin™ HT and FUSE LINK**:

Appendix Y-2	ActivaPin™ HT Surgical Technique
Appendix Y-3	(b)(4)
Appendix Y-4	Device Package Labeling, Bioretec ActivaPin™ HT
Appendix Y-5	Device Package Labeling, FUSE LINK
Appendix Y-6	Instructions for Use Bioretec ActivaPin™ HT
Appendix Y-7	Instructions for Use FUSE LINK
Appendix Y-8	Instructions for Use FUSE LINK Disposable Applicator
Appendix Y-9	Marketing and promotional material for ActivaPin™ HT



P Sterilization and Shelf Life

1 PACKAGING

Information provided with original premarket notification of ActivaPin™ Product Group (K080879) is valid for modified ActivaPin™ Product Group.

2 STERILIZATION

Information provided with original premarket notification ActivaPin™ Product Group is valid (K080879) for modified ActivaPin™ Product Group. The ActivaPin™ HT and Disposable Pin Applicator with K-wire will be packed in a foil pouch and sterilized separately before packaging in the convenience kit.

3 SHELF LIFE

The ActivaPin™ Product Group shelf life is currently 48 months and is not changed in this special 510(k).

3.1 Pyrogenicity

Information provided with original premarket notification of and ActivaPin™ Product Group (K080879) is valid for modified ActivaPin™ Product group.



Q Biocompatibility

Information provided with original premarket notification of ActivaPin™ Product Group (K080879) is valid.

R Software (N.A.)

This section does not apply.

S Electromagnetic Compatibility and Electrical Safety (N.A.)

This section does not apply.



T Performance Testing – Bench

Information provided with original premarket notifications of ActivaPin™ Product Group (K080879) is valid for modified ActivaPin™ Product Group.

U Performance Testing – Animal (N.A.)

This section does not apply.

V Performance Testing – Clinical (N.A.)

This section does not apply.



W References

ANSI/AAMI/ISO 14971:2007 Medical devices — Application of risk management to medical devices



X Kit Certification

I certify that the following components of my kit are either (1) legally marketed pre-Amendments devices, (2) exempt from premarket notification (consistent with the exemption criteria described in the classification regulation(s) and the limitation of exemptions for Section 510(k) of the act (e.g., 862.9), or (3) have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is to be intended (i.e., I am not claiming or causing a new use for the component(s)).

I further certify that these components are not purchased in "bulk", but are purchased in finished form, i.e., they are packaged, labeled, etc., consistent with their pre-Amendments, exemption, or premarket notification criteria and status.

FOOTMIND CONVENIENCE KIT COMPONETS:	FOOTMIND CONVENIENCE KIT LABELING:
ActivaPin™ HT private labeled to FUSE LINK	
Applicator with K-Wire Ø1.6 mm, disposable, for 1.5 mm pins private labeled to FUSE LINK Disposable applicator (K071863)	(b)(4)
(b)(4)	

Simo Hietaniemi
 Chief Executive Officer, Bioretec Ltd.
 December 19th, 2013



Y List of Appendices

Appendix 1	Technical drawings of ActivaPin™ HT
Appendix 2	ActivaPin™ HT Surgical Technique
Appendix 3	(b)(4)
Appendix 4	Device Package Labeling, Bioretec ActivaPin™ HT
Appendix 5	Device Package Labeling, FUSE LINK
Appendix 6	Instructions for Use Bioretec ActivaPin™ HT
Appendix 7	Instructions for Use, FUSE LINK
Appendix 8	Instructions for Use, FUSE LINK Disposable Applicator
Appendix 9	Marketing and promotional material for ActivaPin™ HT
Appendix 10	Online payment confirmation



A Medical Device User Fee Cover Sheet (Form FDA 3601)

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) BIORETEC LTD Hermiankatu 22, Modulight Building Tampere Finland FI-33720 FI 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2. CONTACT NAME Minna Rasanen 2.1 E-MAIL ADDRESS minna.rasanen@bioretec.com 2.2 TELEPHONE NUMBER (include Area code) +358-408681606 2.3 FACSIMILE (FAX) NUMBER (include Area code)	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm) Select an application type:		
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)		

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

- | | |
|---|---|
| <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates | <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population |
| <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only | <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially |

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

19-Dec-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet



Appendix 10

Online payment confirmation

Online Payment
Step 3: Confirm Payment

1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: FDA User Fees

Pay.gov Tracking ID: (b)(4)

Agency Tracking ID: [REDACTED]

Transaction Date and Time: 12/19/2013 03:15 EST

Payment Summary

Address Information

Account Holder BIORETEC

Name: LTD

Billing Address: Hermiankatu 22

Billing Address 2:

City: Tampere

State / Province:

Zip / Postal Code:

Country: FIN

Account Information

Card Type: (b)(4)

Card Number: ***** (b)(4)

Payment Information

Payment Amount: (b)(4)

Transaction Date 12/19/2013 03:15
and Time: EST



B CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET		Form Approval OMB No. 0910-0120 Expiration Date: December 31, 2013 See PRA Statement on page 5.		
Date of Submission December 19th, 2013	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)		
SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Request for Feedback <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)				
SECTION B SUBMITTER, APPLICANT OR SPONSOR				
Company / Institution Name Bioretec Ltd.		Establishment Registration Number (if known)		
Division Name (if applicable)		Phone Number (including area code) (+358) 20 778 9500		
Street Address Hermiankatu 22, Modulight Building		FAX Number (including area code) (+358) 3 317 0225		
City Tampere	State / Province	ZIP/Postal Code FI-33720	Country Finland	
Contact Name Ms. Minna Räsänen (Ms. Minna Veiranto)				
Contact Title Q&RA Manager / R&D Manager		Contact E-mail Address minna.rasanen@bioretec.com / minna.veiranto@bioretec.com		
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)				
Company / Institution Name				
Division Name (if applicable)		Phone Number (including area code)		
Street Address		FAX Number (including area code)		
City	State / Province	ZIP Code	Country	
Contact Name				
Contact Title		Contact E-mail Address		

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (<i>specify</i>): 					
SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Other Reason (<i>specify</i>): 					
SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input checked="" type="checkbox"/> Other Reason (<i>specify</i>): Device modification that does not affect the intended use or alter the fundamental scientific technology of the device.					

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	HTY	2		3		4		
5		6		7		8		

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K080879	ActivaPin™	Bioretec Ltd.
2	K061164	ActivaPin™	Bioretec Ltd.
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
 Pin, fixation

	Trade or Proprietary or Model Name for This Device	Model Number
1	ActivaPin™ HT	1 See Product Reference Codes in Special 510(k) submissio
2	FUSE LINK (private labeled for FOOTMIND, INC.)	2 chapter M (Table M-1)
3		3
4		4
5		5

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code 888.3040	C.F.R. Section (if applicable) 21 CFR 888.3040	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel		

Indications (from labeling)

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Bioretec Ltd.		Establishment Registration Number		
Division Name (if applicable)		Phone Number (including area code) (+358) 20 778 9500		
Street Address Hermiankatu 22, Moduligh Building		FAX Number (including area code) (+358) 3 317 0225		
City Tampere		State / Province	ZIP Code FI-33720	Country Finland
Contact Name Ms. Minna Räsänen	Contact Title Q&RA Manager	Contact E-mail Address minna.rasanen@bioretec.com		

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name (if applicable)		Phone Number (including area code)		
Street Address		FAX Number (including area code)		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address		

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name (if applicable)		Phone Number (including area code)		
Street Address		FAX Number (including area code)		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address		

SECTION I UTILIZATION OF STANDARDS					
Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
1	Standards No.	Standards Organization FDA	Standards Title Guidance Document for Testing Biodegradable Polymer Implant Devices	Version Draft	Date 04/20/1996
2	Standards No.	Standards Organization FDA	Standards Title Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA	Version Second edition	Date 08/30/2002
3	Standards No.	Standards Organization ANSI/AAMI/ISO 14971:2007	Standards Title Medical devices - Application of risk management to medical devicesTest	Version Second edition	Date 3/1/2007
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date
Please include any additional standards to be cited on a separate page.					
<p>This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> <p style="text-align: center;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>					



C 510(k) Cover Letter

Food and Drug Administration *
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Receiver,

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, 21 CFR 807.81(a)(3) and the FDA guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device", Bioretec Ltd. ("Company") is submitting the attached premarket notification for its ActivaPin™ Product group. This premarket notification is Special 510(k): Device Modification for ActivaPin™ Product group to add a modified implant and revising labeling accordingly. This is the only modification to the initial 510(k) K080879 to be cleared. The change does not affect the intended use or alter the fundamental scientific technology of the device. The submission is attached as two copies, one of which is a paper copy and one is an eCopy as required in the FDA Guidance document issued on December 31, 2012 "eCopy Program for Medical Device Submissions". The eCopy is an exact duplicate of the paper copy.

The Bioretec's ActivaPin™ Product group common name is Pin, Fixation. The submission K080879 covered Bioretec ActivaPin™ Product Group including bioabsorbable devices ActivaPin™, ActivaPin™ Fusion, ActivaNail™ Conical and ActivaNail™ Flat. The submission included devices of 1.5 mm, 2.0 mm, 2.7 mm and 3.2 mm diameters with lengths from 5 to 70 mm, and the custom instruments used to implant the devices.

To conform with the FDA's August 12, 2005, Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)'s, the following information concerning the design and use of ActivaPin™ Product group is provided:



Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	-	-
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

As explained in more detail in the attached Special 510(k) notice, the addition to ActivaPin™ Product group, ActivaPin™ HT is substantially equivalent to previously cleared ActivaPin™ (K061164) and ActivaPin™ Product Group (K080879).

In accordance with the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Bioretec Ltd. has submitted the required application fee of \$5,170. A copy of the User Fee Cover Sheet is provided with the attached premarket notification.

Bioretec Ltd. considers its intent to market the ActivaPin™ HT as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company therefore requests that FDA not disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore not disclosable under the Freedom of Information Act even after the existence of this application becomes public. We ask that you consult with the Company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

We trust that the information provided in the Special 510(k) notice is sufficient for FDA to find the modified ActivaPin™ Product group substantially equivalent to its predicate devices for



the listed indication. If you have any additional questions regarding the Special 510(k) notice, please contact me at the number below. Upon clearance of the device, please fax the substantial equivalence letter to me at +358 3 317 0225 and e-mail it to my e-mail address Minna.Rasanen@bioretec.com and the cc e-mail address Minna.Veiranto@bioretec.com.

Sincerely,

A handwritten signature in blue ink, appearing to read "Minna Räsänen".

Minna Räsänen

Quality and Regulatory Affairs Manager

Direct: +358 20 778 9509

Mobile: +358 40 868 1606

Fax: +358 3 317 0225

E-mail: Minna.Rasanen@bioretec.com

Minna Veiranto

R&D Manager

Email: Minna.Veiranto@bioretec.com



H Truthful and Accuracy Statement

I certify that, in my capacity as Chief Executive Officer of Bioretec Ltd., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

A handwritten signature in blue ink, appearing to read "Simo Hietaniemi", is written over a horizontal line.

Simo Hietaniemi

December 19th, 2013

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].



M-2

Appendix 1

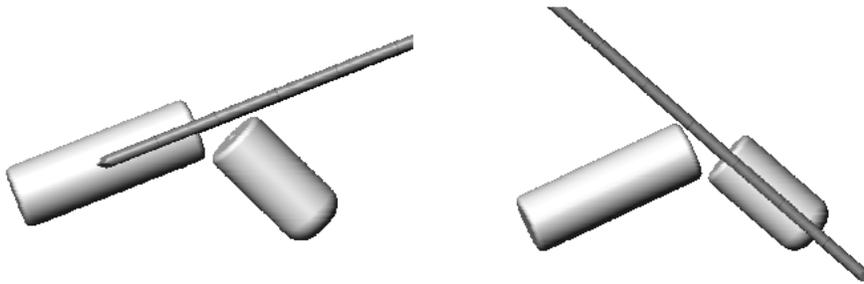
Technical drawing of ActivaPin™ HT



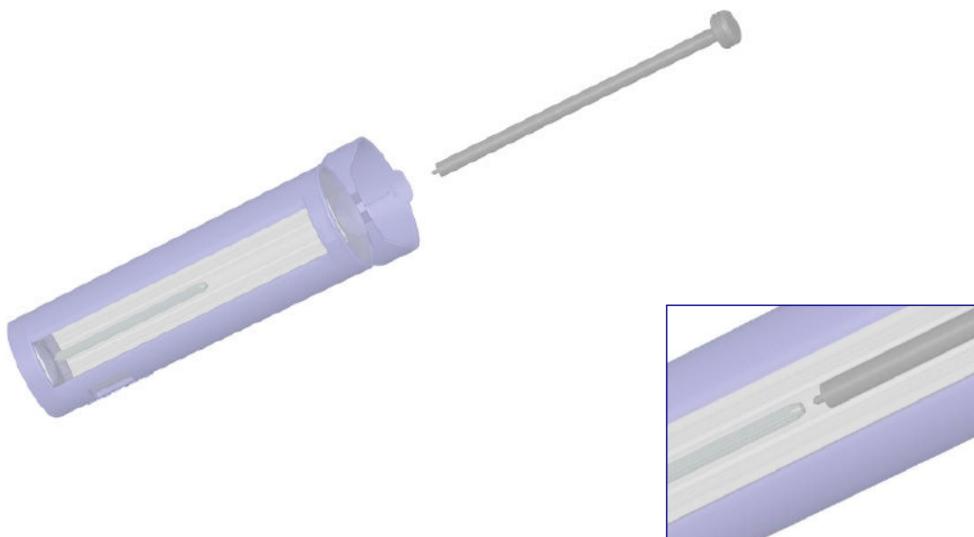
M-2
Appendix 2
ActivaPin™ HT Surgical Technique

SURGICAL TECHNIQUE FOR ActivaPin™ HT

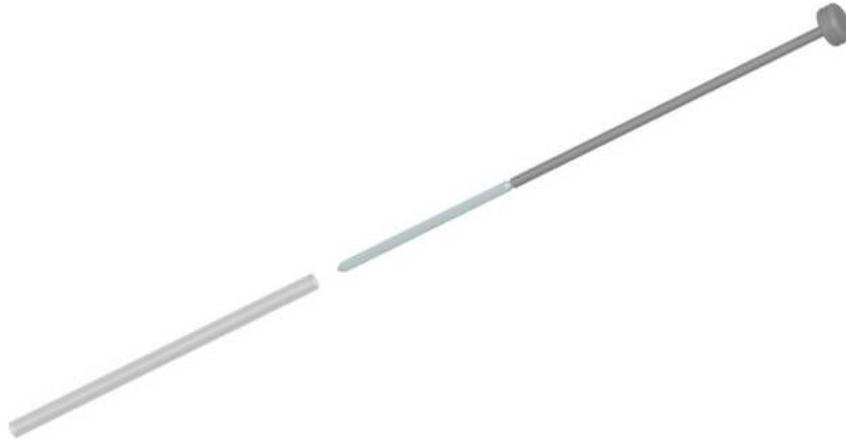
1. Prepare the treated fusion line by applying standard principles of orthopaedics and traumatology.
2. Drill holes which correspond to the implant diameter into the proximal and distal sides of the fusion plane. To prevent overdrilling, multiple reaming with drill bit should be avoided.



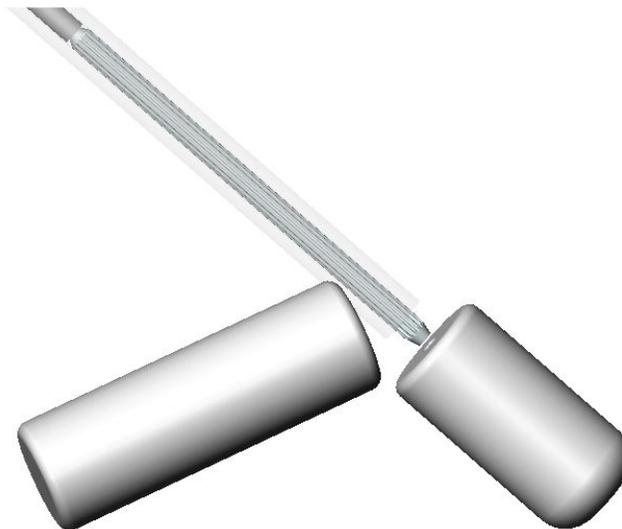
3. Open ActivaPin™ HT HOLDER cap.
4. Pick the implant by pushing the ActivaPin™ HT APPLICATOR PISTON distal head into the ActivaPin™ HOLDER until it is attached to the implant. Notice, either Disposable Pin Applicator or Re-usable Pin Applicator can be used!



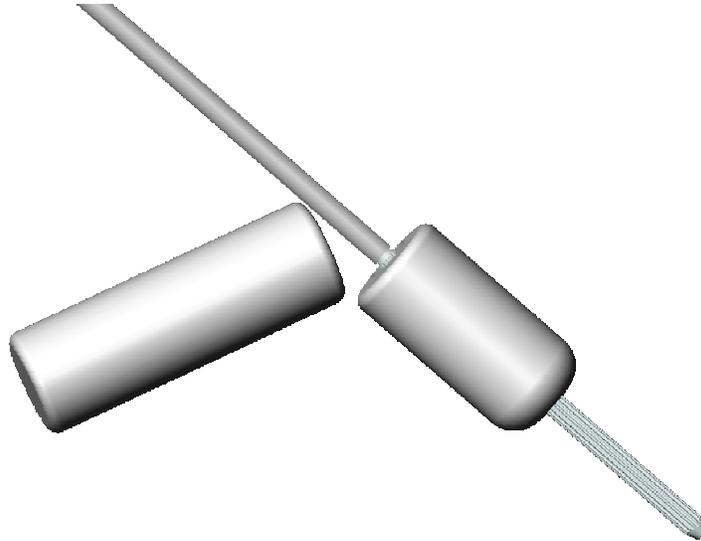
5. Slide attached implant and piston inside to the ActivaPin™ HT Applicator TUBE.



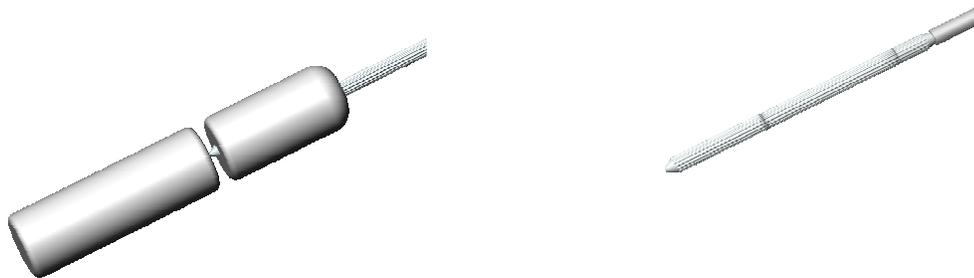
6. Introduce the implant into the hole on the distal side of the fusion plane by sliding the PISTON.
7. During insertion, hold the applicator and the implant parallel to the long axis of the drill hole so that it slides easily to the drill hole. Insert the implant by lightly tapping the PISTON with a mallet.



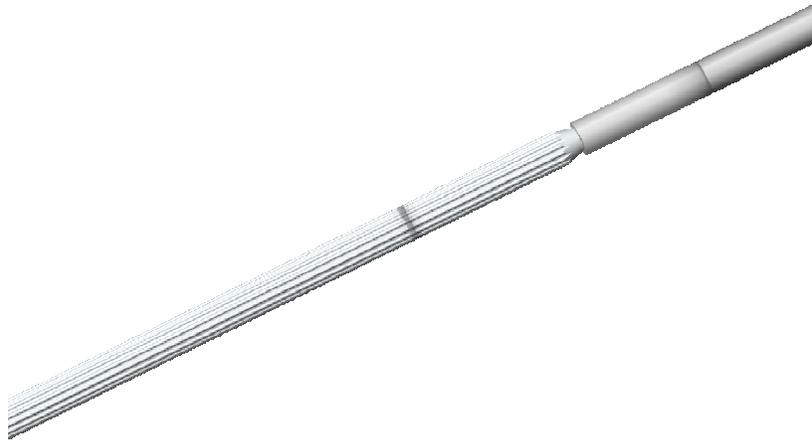
8. Tap the PISTON until the ActivaPin™ HT comes out of the end of the toe and the joint can be closed.



9. Place the distal fusion part in alignment with the proximal part and insert the pin from the distal direction backwards across the joint.



10. If the implant needs to be inserted across the DIP joint, insert the pin antergrade into level with the bone at the tip of the toe. Then take the Applicator TUBE off and insert the pin deeper using only the PISTON until the DIP joint is free.



11. After fixation, the wound is closed in layers applying standard principles of orthopaedics and traumatology.
12. On the basis of surgeon's decision radiographs are taken before wound closure.
13. Meticulous hemostasis and complete primary skin closure over the implant are essential.

Please refer to package insert for indications, contraindications, precautions and warnings. This brochure is presented to demonstrate the surgical technique. Bioretec as the manufacturer of this device does not practice medicine and does not recommend this or any other system for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques for such procedure for use on a specific patient. Bioretec is not responsible for selection on the appropriate product or surgical technique to be utilized for an individual patient.

REMARK:

Prior to using Bioretec Implants examine thoroughly the Instructions For Use - inside each product package.



M-2

Appendix 3

(b)(4) [redacted] Surgical Technique (b)(4) [redacted]

[redacted]

[redacted]

(b)(4)

Surgical Technique

(b)(4)



O-1

Appendix 4

Device Package Labeling, Bioretec ActivaPin™ HT

REF B-APHT-1530 LOT Syynnn 1 x

ActivaPin™ HT 1.5 x 30 mm

HIBC1
+E302BAPHT15309+

HIBC2
+\$\$\$011216SYNNNN+0

Patents: EP 1864616, EP 1902680.
EP, US, FI Patent Pending

MATERIAL PLGA

STERILE R MR

15 °C / 59 °F 30 °C / 86 °F

Bioretec Ltd, Hermiankatu 22, FI-33720 Tampere, Finland

REF B-APHT-1530 LOT Syynnn 1 x

ActivaPin™ HT 1.5 x 30 mm

HIBC1
+E302BAPHT15309+

HIBC2
+\$\$\$011216SYNNNN+0

Patents: EP 1864616, EP 1902680.
EP, US, FI Patent Pending

MATERIAL PLGA

STERILE R MR

15 °C / 59 °F 30 °C / 86 °F

Bioretec Ltd, Hermiankatu 22, FI-33720 Tampere, Finland

REF B-APHT-1530 LOT Syynnn 1 x

ActivaPin™ HT 1.5 x 30 mm

HIBC1
+E302BAPHT15309+

HIBC2
+\$\$\$011216SYNNNN+0

Patents: EP 1864616, EP 1902680.
EP, US, FI Patent Pending

MATERIAL PLGA

STERILE R MR

15 °C / 59 °F 30 °C / 86 °F

Bioretec Ltd, Hermiankatu 22, FI-33720 Tampere, Finland

Warning: Product must be discarded, if temperature exceeds 30 °C (86 °F) to ensure sterility (black dot).

REF B-APHT-1530 1 x

ActivaPin™ HT 1.5 x 30 mm

2013-12 2016-12

LOT Syynnn

HIBC1
+E302BAPHT15309+

HIBC2
+\$\$\$011216SYNNNN+0

STERILE R MR

CE 0344

15 °C / 59 °F 30 °C / 86 °F

Bioretec Ltd, Hermiankatu 22, FI-33720 Tampere, Finland

ActivaPin™ HT 1.5 x 30 mm

REF B-APHT-1530 LOT Syynnn

HIBC2
+E302BAPHT15309+

HIBC1
+\$\$\$011216SYNNNN+0

Patient chart Karta pacjenta
 Patientenkarte Patientkort
 Carte du patient Κάρτα ασθενούς
 Cartella del paziente Patiëntkaart
 Ficha do paciente Potilaskortti
 Tarjeta de paciente Karta pacjenta

REF B-APHT-1530 2016-12 LOT Syynnn
 ActivaPin™ HT
 1.5 x 30 mm
 Bioretec Ltd, Hermiankatu 22, FI-33720 Tampere, FINLAND

REF B-APHT-1530 2016-12 LOT Syynnn
 ActivaPin™ HT
 1.5 x 30 mm
 Bioretec Ltd, Hermiankatu 22, FI-33720 Tampere, FINLAND

REF B-APHT-1530 2016-12 LOT Syynnn
 ActivaPin™ HT
 1.5 x 30 mm
 Bioretec Ltd, Hermiankatu 22, FI-33720 Tampere, FINLAND

REF B-APHT-1530 2016-12 LOT Syynnn
 ActivaPin™ HT
 1.5 x 30 mm
 Bioretec Ltd, Hermiankatu 22, FI-33720 Tampere, FINLAND



O-1
Appendix 5
Device Package Labeling, FUSE LINK



Sample 1. FFP-1530 Foil pouch label



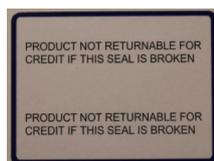
Sample 2. FFP-1530 Patient card



Sample 3. Indicator



Sample 4. FFP-1530 customer package label



Sample 5. Sticker



Sample 6. White box with customer package label, indicator and two stickers



O-1

Appendix 6

Instructions for Use, Bioretec ActivaPin™ HT



ENGLISH / INSTRUCTIONS FOR USE

Bioretec ActivaPin™ HT BIOABSORBABLE IMPLANT

FOR FIXATION OF BONE FRACTURES, OSTEOTOMIES, ARTHRODESES AND OSTEOCHONDRAL FRACTURES IN THE PRESENCE OF APPROPRIATE IMMOBILIZATION

DESCRIPTION AND ACTIONS

Bioretec ActivaPin™ HT is constructed of bioabsorbable poly(L-lactide-co-glycolide) (PLGA). These polymers have a long history of safe medical use and they degrade *in vivo* by hydrolysis into alpha-hydroxy acids that are metabolized by the body. The manufacturing process generates the high initial mechanical strength and stiffness of the implant. Properly used, in the presence of adequate immobilization, ActivaPin™ HT maintains accurate alignment of small bone fractures, apical fragments and osteochondral fragments after surgical procedure. As the operated bone fracture or osteotomy gains strength during healing, ActivaPin™ HT gradually loses its strength, however, maintaining its function at least 8 weeks. Bioabsorption takes place within approximately two years thus eliminating the need for implant removal surgery.

ActivaPin™ HT is sterile, non-collagenous and non-pyrogenic. The material used in the manufacturing of ActivaPin™ HT has a history of safe medical use, and it has been shown to be biocompatible in both animal and clinical evaluations.

ActivaPin™ HT is available in different sizes, and designed to be used with customized instrumentation e.g. the ActivaPin™ HT APPLICATOR. Please refer to the valid catalogue for product codes and sizes available.

ActivaPin™ HT is delivered inside the ActivaPin™ HT HOLDER. This is to protect the pin during storage and delivery, and to enable easy and aseptic implantation of the pin.

INDICATIONS

Bioretec ActivaPin™ HT is 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.

INFORMATION FOR USE

Surgical Considerations and reminders

As for other methods of internal fixation:

- Perioperative antibiotics are recommended.
- Use proper local, regional or general anaesthesia.
- Maintain aseptic conditions during procedure.
- Proper exposure using standard surgical procedure.
- Arteries and nerves should be preserved by careful dissection.



- On the basis of surgeon's decision radiographs are taken before wound closure.
- Meticulous hemostasis and complete primary skin closure over the implant are essential.
- X-ray control can be used for alignment/reduction evaluation.

Surgical Technique

1. Prepare the treated fusion line by applying standard principles of orthopaedics and traumatology.
2. Drill holes which correspond to the implant diameter into the proximal and distal sides of the fusion plane. To prevent overdrilling, multiple reaming with drill bit should be avoided.
3. Open ActivaPin™ HT HOLDER cap.
4. Pick the implant by pushing the ActivaPin™ HT APPLICATOR PISTON distal head into the ActivaPin™ HT HOLDER until it is attached to the implant.
5. Slide attached implant and piston inside to the ActivaPin™ HT Applicator SLEEVE.
6. Introduce the implant into the hole on the distal side of the fusion plane by sliding the PISTON.
7. During insertion, hold the applicator and the implant parallel to the long axis of the drill hole so that it slides easily to the drill hole. Insert the implant by lightly tapping the PISTON with a mallet.
8. Tap the PISTON until the ActivaPin™ HT comes out of the end of the toe and the joint can be closed.
9. Place the distal fusion part in alignment with the proximal part and insert the pin from the distal direction backwards across the joint. After insertion of the implant, it is impossible to correct the alignment of the implant by rotating. If the alignment is incorrect, the distal part can be pulled off from the fusion implant and repositioned in a correct angular position or the implant can be removed by overdrilling.
10. If the implant needs to be inserted across the DIP joint, insert the pin antegrade into level with the bone at the tip of the toe. Then take the Applicator TUBE off and insert the pin deeper using only the PISTON until the DIP joint is free.
11. After fixation, the wound is closed in layers applying standard principles of orthopaedics and traumatology.

Postoperative Reminders

- Use appropriate additional immobilization (e.g. suitable cast, brace and/or crutches) during bone healing.
- Provide the patient with detailed instructions for postoperative care.
- The type of fracture will determine the nature of postoperative weight bearing and rehabilitation regimen.
- X-ray, CT or MRI control can be used to evaluate bone healing.

PRECAUTIONS AND WARNINGS

- ActivaPin™ HT is supplied sterile for single patient use only.
- DO NOT reuse, reprocess or re-sterilize by any method. Reusing, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reusing, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- DO NOT use ActivaPin™ HT if sterile barrier of the package is damaged. Unused pins from damaged or opened packages must be discarded. This is because the pin is no longer sterile and therefore may cause infection. In addition the pin may no longer biodegrade as specified.
- Specialized ActivaPin™ HT instruments are available and must be used to assure the accurate implantation of ActivaPin™ HT.



- DO NOT cut the implant before insertion. When necessary, clamps, scissors, oscillating saw, or a hot wire can be used to modify the implant during the fixation procedure.
- When using ActivaPin™ HT intra-articularly both ends of the implant must be buried inside the bone to avoid the mechanical irritation inside the joint and risk of synovitis.
- Disposal of leftover product materials and packaging should be done in accordance with hospital, administrative and/or local government policy.
- DO NOT use implant beyond the expiration date on the label.
- DO NOT use implant if the temperature indicator of the package is activated (i.e. dot colour has changed from white to black).
- Surgical instruments are subject to wear with normal usage and may break. Surgical instruments are only to be used for their intended purpose. All instruments are to be regularly inspected for wear and damage. Use only the customized instrumentation e.g. the ActivaPin™ APPLICATOR.
- The patient should be warned that premature bending, loosening, fracture or migration of the implants may result from too early weight bearing or physical activity, stressing the fixation..
- Transient sinus formation may occur in sterile circumstances. Aspiration (simple drainage) may yield implant remnants and usually results in healing of the sinuses without adverse effect to healing of the fracture.
- The surgeon should choose the correct devices, method of application and surgical procedure prior to performing the surgery. Incorrect selection, placement, positioning, or fixation of the implant can cause subsequent undesirable results. Additional appropriate immobilization should be considered by the treating physician in the use of ActivaPin™ HT.
- Due to the nature of ActivaPin™ HT as a small size fixation implant, appropriate consideration and immobilization should be used in applications involving diaphyseal or weight bearing cancellous bone.

SPECIAL PATIENT POPULATIONS

The effect of the ActivaPin™ HT upon the healing of growth plate has not been tested clinically.

ADVERSE EFFECTS

Complications are similar to those with any method of internal fixation:

- Infections, both deep and superficial related to surgery performed.
- Allergic and other responses to anaesthetic agents and device materials.
- Neurovascular injuries can occur due to surgical trauma.
- Internal repair using the ActivaPin™ HT (as for other similar fixation devices) may be associated with transient local fluid accumulation or sinus formation.

CAUTION

Federal law (USA) restricts this device to sale by, or on the order of, a licensed physician.

STERILITY

ActivaPin™ HT implants are delivered sterile, DO NOT RE-STERILIZE by any method.

ActivaPin™ HT implants have been sterilized with gamma irradiation (SAL 10⁻⁶). Use the pin immediately after opening the sterile seal. Use only devices that are contained in unopened and undamaged packages. DO NOT use implant beyond the expiration date on the label.

STORAGE

Store at room temperature (15 to 30°C or 59 to 86°F) and at a normal relative humidity. Product must be discarded, if temperature exceeds 49°C or 120°F as shown by the temperature indicator on the package.



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FI-33720 Tampere, Finland
Tel. +358 20 778 9500
Fax. +358 3 317 0225
Bioretec@bioretec.com
www.bioretec.com



Symbols:

Symbol	Meaning
	Catalogue number
	Lot Number
	Use by - year and month
	Sterilized by Radiation
	See Instructions for Use
	Do not reuse
	Manufacturer
	MR safe
	Material of product
Rx Only	U.S. Federal law restricts this device to sale, distribution, or use by or on the order of a physician
	Date of manufacture
	Temperature limitation
	Keep dry



O-1
Appendix 7
Instructions for Use, FUSE LINK



ENGLISH / INSTRUCTIONS FOR USE

FUSE LINK BIOABSORBABLE IMPLANT

FOR FIXATION OF BONE FRACTURES, OSTEOTOMIES, ARTHRODESES AND OSTEOCHONDRAL FRACTURES IN THE PRESENCE OF APPROPRIATE IMMOBILIZATION

DESCRIPTION AND ACTIONS

FUSE LINK is constructed of bioabsorbable poly(L-lactide-co-glycolide) (PLGA). These polymers have a long history of safe medical use and they degrade *in vivo* by hydrolysis into alpha-hydroxy acids that are metabolized by the body. The manufacturing process generates the high initial mechanical strength and stiffness of the implant. Properly used, in the presence of adequate immobilization, **FUSE LINK** maintains accurate alignment of small bone fractures, apical fragments and osteochondral fragments after surgical procedure. As the operated bone fracture or osteotomy gains strength during healing, **FUSE LINK** gradually loses its strength, however, maintaining its function at least 8 weeks. Bioabsorption takes place within approximately two years thus eliminating the need for implant removal surgery.

FUSE LINK is MR Safe, sterile, non-collagenous, non-pyrogenic. The material used in the manufacturing of **FUSE LINK** has a history of safe medical use, and it has been shown to be biocompatible in both animal and clinical evaluations.

FUSE LINK is designed to be used with customized instrumentation **FUSE LINK Disposable Applicator**. Please refer to the valid catalogue for product codes and sizes available.

FUSE LINK is delivered inside the pin holder. This is to protect the pin during storage and delivery, and to enable easy and aseptic implantation of the pin.

INDICATIONS

FUSE LINK is 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.

INFORMATION FOR USE

Surgical Considerations and reminders

As for other methods of internal fixation:

- i Perioperative antibiotics are recommended.
- i Use proper local, regional or general anaesthesia.
- i Maintain aseptic conditions during procedure.
- i Proper exposure using standard surgical procedure.
- i Arteries and nerves should be preserved by careful dissection.
- i On the basis of surgeon's decision radiographs are taken before wound closure.
- i Meticulous hemostasis and complete primary skin closure over the implant are essential.



- i X-ray control can be used for alignment/reduction evaluation.

Surgical Technique

1. Prepare the treated fusion line by applying standard principles of orthopaedics and traumatology.
2. Drill holes which correspond to the implant diameter into the proximal and distal sides of the fusion plane. To prevent overdrilling, multiple reaming with drill bit should be avoided.
3. Prepare the fusion surfaces e.g. with (b)(4).
4. Open the pin holder cap.
5. Pick the implant by pushing the **FUSE LINK Disposable Applicator PISTON** distal head into the pin holder until it is attached to the implant.
6. Slide attached implant and piston inside to the **FUSE LINK Disposable Applicator SLEEVE**.
7. Introduce the implant into the hole on the distal side of the fusion plane by sliding the **PISTON**.
8. During insertion, hold the applicator and the implant parallel to the long axis of the drill hole so that it slides easily to the drill hole. Insert the implant by lightly tapping the **PISTON** with a mallet.
9. Tap the **PISTON** until the **FUSE LINK** comes out of the end of the toe and the joint can be closed.
10. Place the distal fusion part in alignment with the proximal part and insert the pin from the distal direction backwards across the joint. After insertion of the implant, it is impossible to correct the alignment of the implant by rotating. If the alignment is incorrect, the distal part can be pulled off from the fusion implant and repositioned in a correct angular position or the implant can be removed by overdrilling.
11. If the implant needs to be inserted across the DIP joint, insert the pin antergrade into level with the bone at the tip of the toe. Then take the **APPLICATOR SLEEVE** off and insert the pin deeper using only the **PISTON** until the DIP joint is free.
12. After fixation, the wound is closed in layers applying standard principles of orthopaedics and traumatology.

Postoperative Reminders

- i Use appropriate additional immobilization (e.g. suitable cast, brace and/or crutches) during bone healing.
- i Provide the patient with detailed instructions for postoperative care.
- i The type of fracture will determine the nature of postoperative weight bearing and rehabilitation regimen.
- i X-ray, CT or MRI control can be used to evaluate bone healing.

PRECAUTIONS AND WARNINGS

- i **FUSE LINK** is supplied sterile for single patient use only.
- i DO NOT reuse, reprocess or re-sterilize by any method. Reusing, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reusing, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- i DO NOT use **FUSE LINK** if sterile barrier of the package is damaged. Unused pins from damaged or opened packages must be discarded. This is because the pin is no longer sterile and therefore may cause infection. In addition the pin may no longer biodegrade as specified.
- i Specialized **FUSE LINK** instruments are available and must be used to assure the accurate implantation of **FUSE LINK**.
- i DO NOT cut the implant before insertion. When necessary, clamps, scissors, oscillating saw, or a hot wire can be used to modify the implant during the fixation procedure.



- i When using **FUSE LINK** intra-articularly both ends of the implant must be buried inside the bone to avoid the mechanical irritation inside the joint and risk of synovitis.
- i Disposal of leftover product materials and packaging should be done in accordance with hospital, administrative and/or local government policy.
- i DO NOT use implant beyond the expiration date on the label.
- i DO NOT use implant if the temperature indicator of the package is activated (i.e. dot colour has changed from white to black).
- i Use only the customized instrumentation **FUSE LINK Disposable Applicator**.
- i The patient should be warned that premature bending, loosening, fracture or migration of the implants may result from too early weight bearing or physical activity, stressing the fixation.
- i Transient sinus formation may occur in sterile circumstances. Aspiration (simple drainage) may yield implant remnants and usually results in healing of the sinuses without adverse effect to healing of the fracture.
- i The surgeon should choose the correct devices, method of application and surgical procedure prior to performing the surgery. Incorrect selection, placement, positioning, or fixation of the implant can cause subsequent undesirable results. Additional appropriate immobilization should be considered by the treating physician in the use of **FUSE LINK**.
- i Due to the nature of **FUSE LINK** as a small size fixation implant, appropriate consideration and immobilization should be used in applications involving diaphyseal or weight bearing cancellous bone.

SPECIAL PATIENT POPULATIONS

The effect of the **FUSE LINK** upon the healing of growth plate has not been tested clinically.

ADVERSE EFFECTS

Complications are similar to those with any method of internal fixation:

- i Infections, both deep and superficial related to surgery performed.
- i Allergic and other responses to anaesthetic agents and device materials.
- i Neurovascular injuries can occur due to surgical trauma.
- i Internal repair using the **FUSE LINK** (as for other similar fixation devices) may be associated with transient local fluid accumulation or sinus formation.

CAUTION

Federal law (USA) restricts this device to sale by, or on the order of, a licensed physician.

STERILITY

FUSE LINK implants are delivered sterile, DO NOT RE-STERILIZE by any method.

FUSE LINK implants have been sterilized with gamma irradiation (SAL 10^{-6}). Use the pin immediately after opening the sterile seal. Use only devices that are contained in unopened and undamaged packages. DO NOT use implant beyond the expiration date on the label.

STORAGE

Store at room temperature (15 to 30°C or 59 to 86°F) and at a normal relative humidity. Product must be discarded, if temperature exceeds 49°C or 120°F as shown by the temperature indicator on the package.



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 support@FootMind.com

Symbols:

Symbol	Meaning
	Catalogue number
	Lot Number
	Use by - year and month
	Sterilized by Radiation
	See Instructions for Use
	Do not reuse
	Manufacturer
	MR safe
	Material of product
Rx Only	U.S. Federal law restricts this device to sale, distribution, or use by or on the order of a physician
	Date of manufacture
	Temperature limitation
	Keep dry

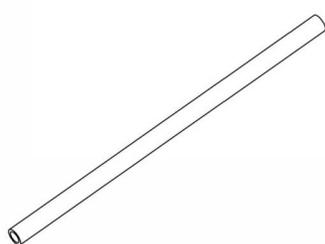


O-1
Appendix 8
Instructions for Use, FUSE LINK Disposable
Applicator

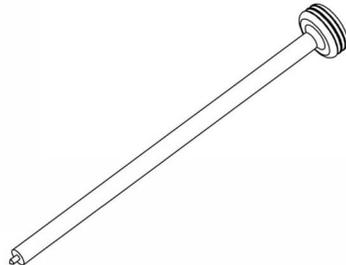


INSTRUCTIONS FOR USE

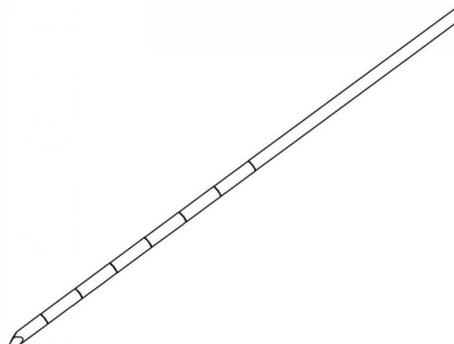
FUSE LINK Disposable Applicator Instrument Set for FUSE LINK



SLEEVE



PISTON



K-WIRE

DESCRIPTION

FUSE LINK Disposable Applicator instrument set contains three different parts: sleeve, piston and K-wire.

FUSE LINK Disposable Applicator instrument set is supplied sterile and validated for single use only. Please refer to the current catalogue for product codes and sizes available.

APPLICATION

FUSE LINK Disposable Applicator instrument set is designed to aid the surgeon in installation of FUSE LINK. The surgical techniques for implantation of the FUSE LINK describe the proper application of specialty instrumentation and should be read and understood by the surgeon prior to use.

WARNINGS

- FUSE LINK Disposable Applicator instrument set is supplied sterile and validated for single use only. DO NOT reuse, reprocess or re-sterilize by any method. Reusing, reprocessing or re-sterilizing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reusing, reprocessing or re-sterilizing may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Manufacturer will not take responsibility or guarantee safe use of these products, if the product is re-cleaned or/and re-sterilized.
- FUSE LINK Disposable Applicator instrument set should never be used for tasks it was not specifically designed to perform. Misuse of an instrument may damage the instrument and implant, and may cause trauma to the patient and/or operating room personnel.
- If not handled correctly, instruments with cutting edges or sharp corners may compromise sterility by tearing surgical gloves.



- If an instrument tip is bent, chipped, or otherwise damaged the instrument should be replaced. Attempts to straighten bends are not advised as the metallurgical integrity of the metal may be compromised in the process, and the instrument may subsequently break during use.

LIMITED WARRANTY

Bioretec Ltd. guarantees that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse, or improper handling of the product subsequent to receipt by the purchaser. Bioretec Ltd. does not warrant the outcome of the surgical procedure.

CAUTION

Federal law (USA) restricts this device to sale by, or on the order of, a licensed physician.

STERILITY

FUSE LINK Disposable Applicator instrument set is delivered sterile. DO NOT RE-STERILIZE by any method. FUSE LINK Disposable Applicator instrument set has been sterilized with gamma irradiation (SAL 10^{-6}). Use the device immediately after opening the sterile seal. Use only devices that are contained in unopened and undamaged packages. DO NOT use the device beyond the expiration date on the label.

PRODUCT CODES

FDPA-15 FUSE LINK Disposable Applicator 1.5 mm

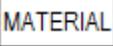


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Symbol	Meaning
	Catalogue number
	Lot Number
	Use by - year and month
	Sterilized by Radiation
	See Instructions for Use
	Do not reuse
	Manufacturer
	Material of product
Rx Only	U.S. Federal law restricts this device to sale, distribution, or use by or on the order of a physician
	Date of manufacture
	Temperature limitation
	Keep dry



O-1
Appendix 9
Marketing and promotional material for ActivaPin™
HT



bioretec

Knowledge within.

The Techniques of the ActivaPin™ HT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

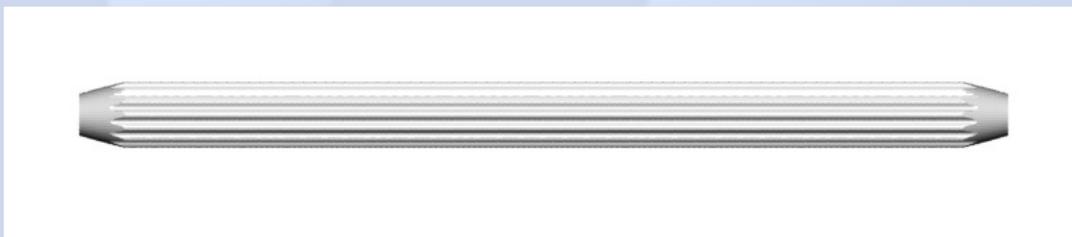
DESCRIPTION AND ACTIONS:

The **ActivaPin™ HT** bioabsorbable pins are constructed of bioabsorbable lactic/glycolic acid copolymer (PLGA). These polymers have a long history of safe medical use and they degrade *in vivo* by hydrolysis into alpha-hydroxy acids that are metabolized by the body. The manufacturing process generates the high initial mechanical strength and stiffness of the Pins. Properly used, in the presence of adequate immobilization, the **ActivaPin™ HT** maintains accurate alignment of small bone fractures, apical fragments and osteochondral fractures after surgical procedure. As the operated bone fracture or osteotomy gains strength during healing, the **ActivaPin™ HT** gradually loses its strength, however, maintaining its function at least 8 weeks. Bioabsorption takes place approximately within two years thus eliminating the need for implant removal surgery.

The **ActivaPin™ HT** is sterile, non-collagenous and non-pyrogenic. The material used in the manufacturing of **ActivaPin™ HT** has a history of safe medical use, and has been shown to be biocompatible in both animal and clinical evaluations.

The **ActivaPin™ HT** implants are also available in different sizes, and designed to be used with customized instrumentation e.g. the **ActivaPin™ HT APPLICATORS** and **ARTHROSCOPIC** instruments. Please refer to the valid catalogue for product codes and sizes available.

ActivaPin™ HT is delivered inside the **ActivaPin™ HT HOLDER**. It is made to protect the pin during storage/delivery, and for easy and aseptic implantation of the pin.



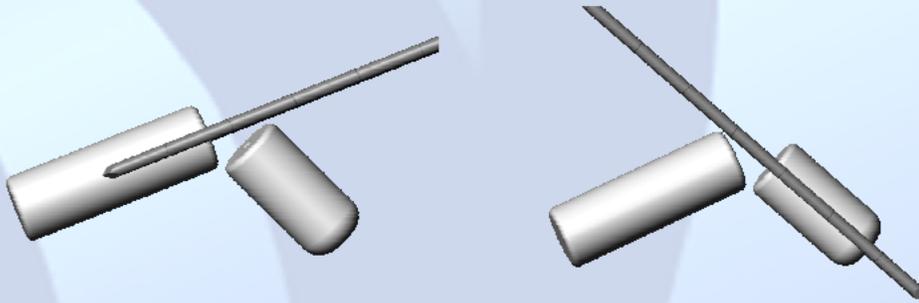
ActivaPin™ HT Offers:

- **Self-Locking SL™**
- **Grooved surface design offers:**
 - **The instant locking effect into the drill hole.**
 - **Better performance with inaccurate drill holes due to e.g. multiple reaming.**
 - **Improved rotation stability.**
 - **Channels along the implant enabling improved vascularization, blood flow and interstitial fluid flow (ISF) required for effective bone healing.**
- **Isoelasticity; the bending modulus is closer to the value of cortical bone compared to metallic implants.**
- **High Strength properties offer easy insertion and safe medical use.**
- **No stress shielding.**
- **No need for removal operation.**
- **Bioabsorption eliminates risks of long term complications.**
- **Implant is supplied Gamma sterilized – safe, free of gas remnants, reduced cross infection risk.**
- **Pin material allows bending and modification during the operation.**
- **Improved insertion and fusion properties with swa surgical heads**

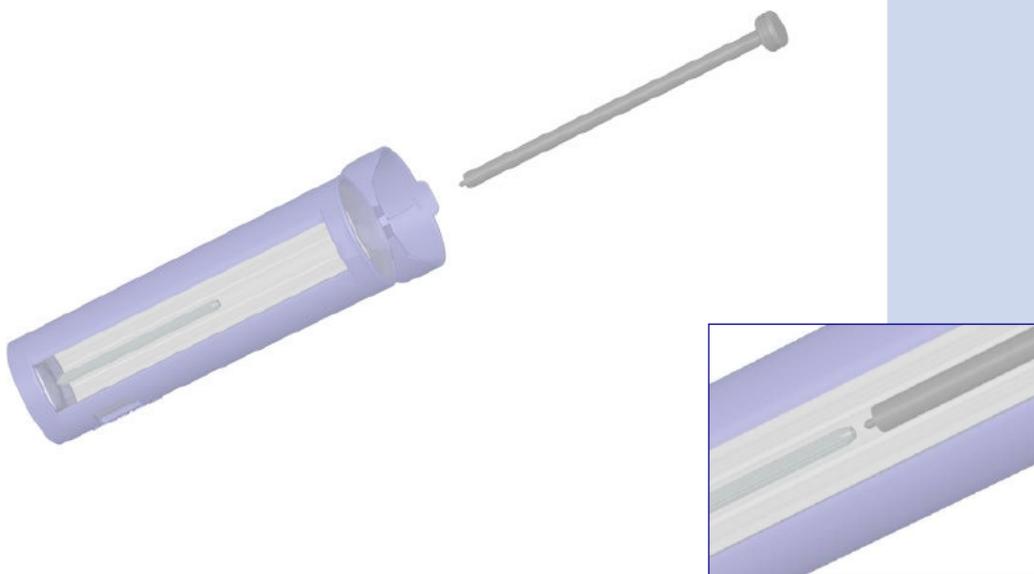
SURGICAL TECHNIQUE

SURGICAL TECHNIQUE FOR ActivaPin™ HT

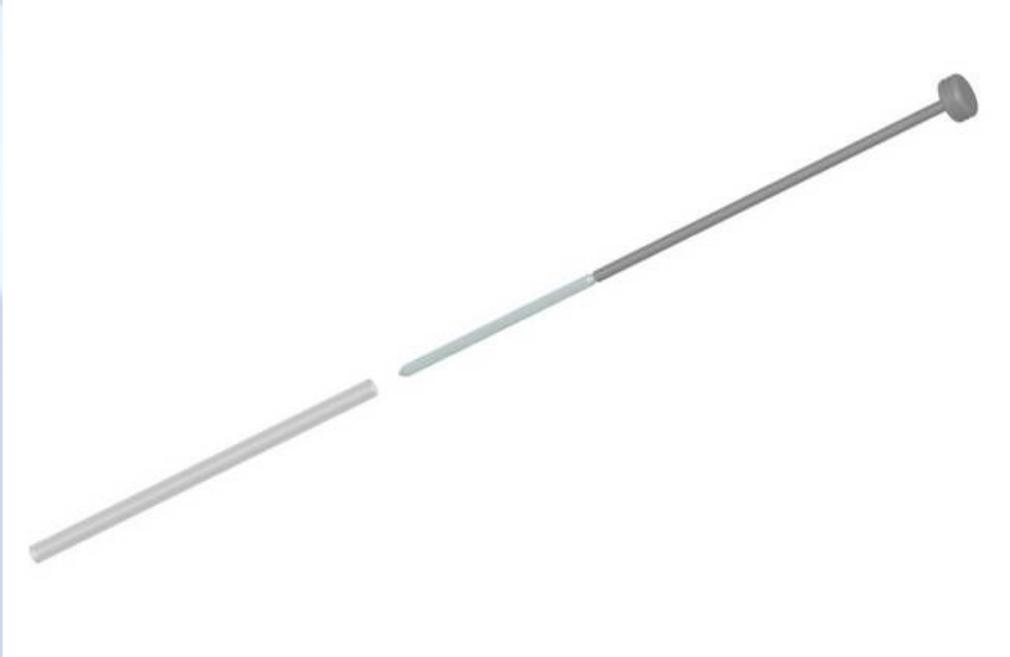
1. Prepare the treated fusion line by applying standard principles of orthopaedics and traumatology.
2. Drill holes which correspond to the implant diameter into the proximal and distal sides of the fusion plane. To prevent overdrilling, multiple reaming with drill bit should be avoided.



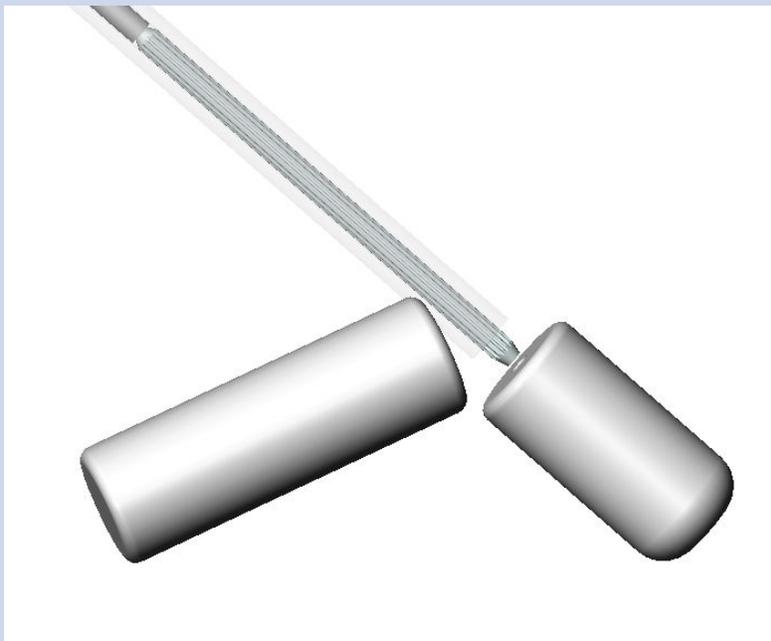
3. Open ActivaPin™ HT HOLDER cap.
4. Pick the implant by pushing the ActivaPin™ HT APPLICATOR PISTON distal head into the ActivaPin™ HOLDER until it is attached to the implant. Notice, either Disposable Pin Applicator or Re-usable Pin Applicator can be used!



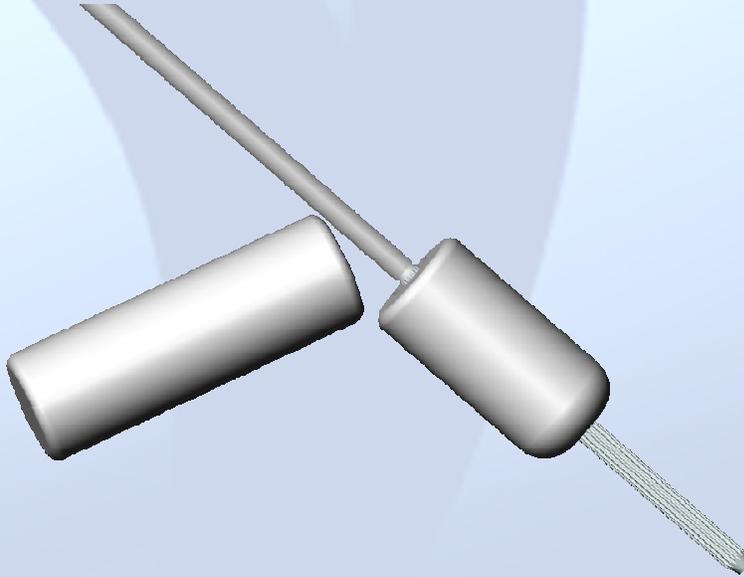
5. Slide attached implant and piston inside to the ActivaPin™ HT Applicator TUBE.



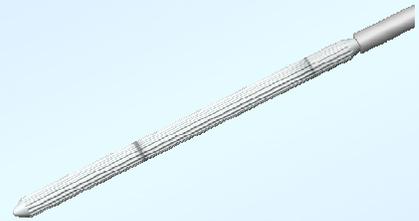
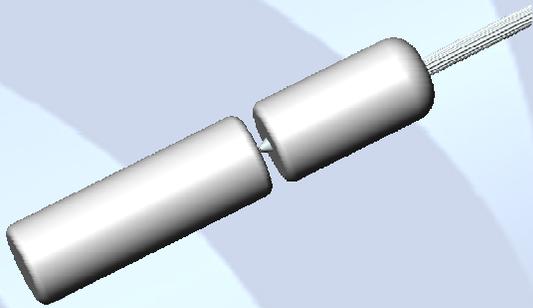
6. Introduce the implant into the hole on the distal side of the fusion plane by sliding the PISTON.
7. During insertion, hold the applicator and the implant parallel to the long axis of the drill hole so that it slides easily to the drill hole. Insert the implant by lightly tapping the PISTON with a mallet.



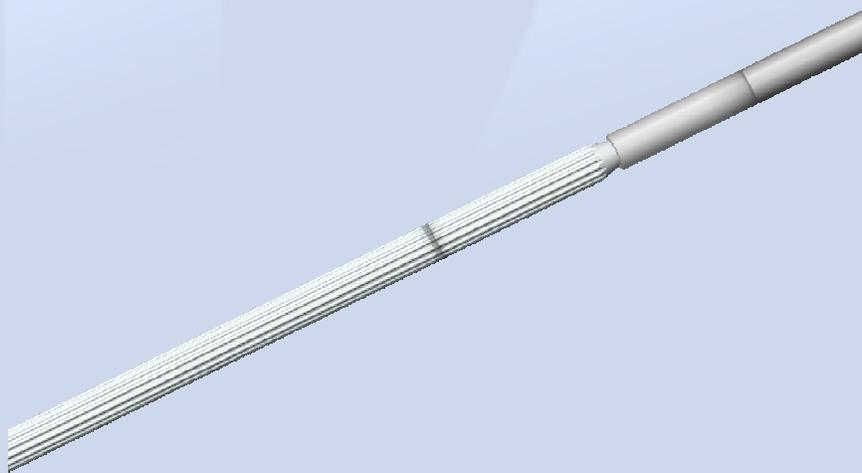
8. Tap the PISTON until the ActivaPin™ HT comes out of the end of the toe and the joint can be closed.



9. Place the distal fusion part in alignment with the proximal part and insert the pin from the distal direction backwards across the joint.



10. If the implant needs to be inserted across the DIP joint, insert the pin antergrade into level with the bone at the tip of the toe. Then take the Applicator TUBE off and insert the pin deeper using only the PISTON until the DIP joint is free.



11. After fixation, the wound is closed in layers applying standard principles of orthopaedics and traumatology.
12. On the basis of surgeon's decision radiographs are taken before wound closure.
13. Meticulous hemostasis and complete primary skin closure over the implant are essential.

ORDERING INFORMATION

REMARK:

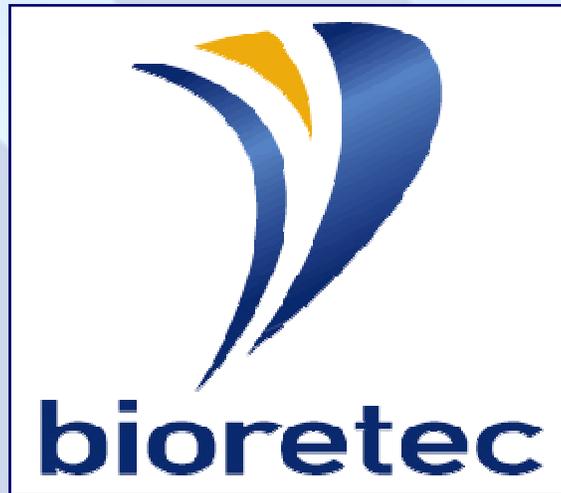
Prior to using Bioretec Implants examine thoroughly the Instructions For Use - inside each product package.

Product Description Table of ActivaPin™ HT

Product Description	Product Reference Code	Diameter	Length
ActivaPin™ HT 1.5 mm x 20 mm	B-APHT-1520	1.5 mm	20 mm
ActivaPin™ HT 1.5 mm x 30 mm	B- APHT-1530	1.5 mm	30 mm
ActivaPin™ HT 1.5 mm x 40 mm	B- APHT-1540	1.5 mm	40 mm
ActivaPin™ HT 1.5 mm x 50 mm	B- APHT-1550	1.5 mm	50 mm
ActivaPin™ HT 1.5 mm x 60 mm	B- APHT-1560	1.5 mm	60 mm
ActivaPin™ HT 1.5 mm x 70 mm	B- APHT-1570	1.5 mm	70 mm

ActivaPin™ HT Instruments:

Product Description	Product Reference Code
Applicator for 1.5 mm ActivaPin™	B-IP-1500
Drill Bit Ø 1.5 mm	B-IP-1503
K-wires (10 pcs) for 1.5 mm ActivaPin™	B-IP-1501
Disposable Pin Applicator 1.5 mm	B-DIP-1500



MANUFACTURER

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DISTRIBUTOR

Final Draft 12-2013



COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

From: Reviewer Name Tara N. Shepherd
Subject: 510(k) Number K133950
To: The Record

Please list CTS decision code: SE - Substantially Equivalent

- Refused to Accept (Note: this is considered the first review cycle. See [screening checklist](#).)
- Hold (Additional Information or Telephone Hold)
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e. SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page (<i>Attach IFU</i>)	X	
510(k) Summary or 510(k) Statement (<i>Attach Summary or Statement</i>)	X	
Truthful and Accurate Statement (<i>Must be present for a Final Decision</i>)	X	
Is the device Class III?		X
Does firm reference standards? (If yes, please attach Form 3654 .)		X
Is this a combination product?		X
Is this a reprocessed single use device? (See Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices .)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X

Nanotechnology		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Regulation Number:	21 CFR 888.3040
Class:	II
Product Code:	HTY
Additional Product Codes:	

Digital Signature Concurrence Table (Not all signatures may be required)	
Branch Chief Sign-Off	Elizabeth L. Frank - S 2014.01.22 12:57:16 -05'00'
Division Sign-Off	Ronald P. Jean - S 2014.01.22 13:03:18 -05'00'