

JUL 16 2004

**IBt**

21 June 2004

CONFIDENTIAL

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Title: **Premarket Notification: Special 510(k) Device Modification – EZ-Pak™**

*K041702*  
**510(K) SUMMARY**

**Applicant /Manufacturing Site:**

IBt s.a.  
Zone Industrielle C  
7180 Seneffe – Belgium  
Tel: (+32) 64 / 520 811  
Fax: (+32) 64 / 520 801

Establishment Registration Number: 9031509 (IBt s.a.)  
Contact Person IBt s.a.: Sylviane Berger, Management Representative  
E-mail: sberger@brachytherapy.be

**Official Correspondent:**

IBt, Inc.  
6000 Live Oak Parkway, Suite 107  
Norcross, GA 30093  
Tel: (770) 582 0662  
Fax: (770) 582 0657  
Establishment Registration Number: 9035105 (IBt, Inc.)  
Contact Person IBt, Inc.: Ruth Feicht, President  
E-mail: rfeicht@ibt4seeds.com

**Device Information**

Trade Name: EZ-Pak (EZ-Pak™ is a Trademark of IBt s.a.)  
Model Number: Not Applicable  
Common Name of Device: Preloaded needles / cartridges, sealed source; seed; interstitial implant

**Type of 510(k) Submission:** Special 510(k) Device Modification

**Classification Information**

Classification: Radionuclide Brachytherapy Source Class II device  
Class of Device: 21 CFR 892.5730, Class II  
Product Code: 90-KXX

**Intended Use**

EZ-Pak™ is a packaging change to InterSource<sup>103</sup> (#K973328), InterSource<sup>125</sup> (#K9984235) and InterStrand® (#K011155). There is no change in the intended use of these cleared sources. Please see the referenced Premarket Notification documents for Statements of Intended Use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 16 2004

Ms. Ruth Feicht  
President  
International Brachytherapy, Inc.  
6000 Live Oak Parkway, Suite 107  
NORCROSS GA 30093

Re: K041702  
Trade/Device Name: EZ-Pak Preload Needles  
Regulation Number: 21 CFR 892.5730  
Regulation Name: Radionuclide  
brachytherapy source  
Regulatory Class: II  
Product Code: 90 KXX  
Dated: June 21, 2004  
Received: June 23, 2004

Dear Ms. Feicht:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

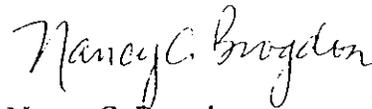
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): k041702

Device Name: EZ-Pak Preloaded Needles

### Indications For Use:

The sources in EZ-Pak Preloaded Needles are indicated for interstitial implantation of select localized tumors with low to moderate radiosensitivity. They are used either as primary treatment for tumors such as those of the head, lung, neck, pancreas, prostate, and unresectable tumors, or for residual disease after excision of the primary tumor.

The source in EZ-Pak Preloaded Needles are indicated for use concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy.

Prescription Use  /   
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K041702