K042110

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SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the summary for the BeamCath.

SUBMITTER'S NAME:	Beampoint AB
ADDRESS:	Box 7984, S-907 19 Umeå Sweden
CONTACT PERSON:	Constance Bundy
TELEPHONE NUMBER:	763-574-1976
FAX NUMBER:	763-571-2437
DATE OF SUBMISSION:	4 August 2004

1. **Identification of device**
   Proprietary Name: BeamCath
   Common Name: Urological Catheter Patient Positioning Device
   Classification Status: This device is classified as a Patient Positioning System, an accessory to Radiation Therapy Medical Systems, Class II per regulation 892.5050. In addition, its configuration and material composition are similar to Urological Catheters, Class II per regulation 876.5130.
   Product Codes: IYE (Patient Positioning System Accessory), EZL (Foley Catheter),

2. **Equivalent devices**
   The BeamCath combines the function of a radiographic positioning device with the configuration of a urological Foley catheter. Beampoint believes that, from a patient positioning indication for use, BeamCath is substantially equivalent to predicate systems such as BrainLAB ExacTrac (K003285) and NOMOS BAT (K981424) devices. In addition, Beampoint believes that, from a configuration and material composition standpoint, the BeamCath is substantially equivalent to the predicate urological catheters Rusch Simplastic Councill Tip Catheter (K974419) and the Kendall Ultramer Coude Foley Catheter (K990500).

3. **Description of the Device**
   The BeamCath is a positioning device used with external beam conformal radiation therapy for visualizing the prostate position during treatment of prostate cancer. The BeamCath combines the function of a radiographic positioning device with the configuration of a urological Foley catheter. The BeamCath configuration and material composition are similar to urological catheters with a balloon retention mechanism. The device is

disposable, sterile and intended for single use. The BeamCath is approximately 430 mm in length and 14 French diameter with a balloon size of 10 ml. The device consists of a PVC connector with outlet lumen for instillation of contrast into the bladder and air-inflation lumen for balloon function; PVC tubing with tantalum radiopaque markers; and a natural latex balloon retention mechanism.

The BeamCath is introduced into the urethra as is a sterile urological catheter and is retained in place by inflating the balloon tip. Its radiopaque markers aid in radiographic visualization of the prostate position for planning, simulation and treatment of prostate cancer using dose escalation radiotherapy. Precise positioning of the prostate allows for more precise dose radiation treatment without excessive side effects to surrounding tissue.

4. **Intended use**

The BeamCath is a positioning device used with external beam conformal radiation therapy for visualizing the prostate position during treatment of prostate cancer. The BeamCath is introduced into the urethra as is a sterile urological catheter and is retained in place by inflating the balloon tip. Its radiopaque markers aid in radiographic visualization of the prostate position for planning, simulation and treatment of prostate cancer using dose escalation radiotherapy.

5. **Technological characteristics, comparison to predicate devices.**

The BeamCath combines the function of a radiographic positioning device with the configuration of a urological Foley catheter. The BeamCath is similar in its indications for use as a patient positioning system to the ExacTrac and BAT systems. All the systems use standard visualization techniques that have a long history of use.

Patient Positioning Comparison Table

Device	BeamCath	BrainLAB ExacTrac	NOMOS BAT
Indications for Use	The BeamCath is a positioning device used with external beam conformal radiation therapy for visualizing the prostate position during treatment of prostate cancer. The BeamCath is introduced into the urethra as is a sterile urological catheter and is retained in place by inflating the balloon tip. Its radiopaque markers aid in radiographic visualization of the prostate position for planning, simulation and treatment of prostate cancer using dose escalation radiotherapy.	ExacTrac is a system that is intended to be used to place patients at the isocenter of a linear accelerator for stereotactic radiotherapy procedures. The ExacTrac system uses optical tracking of infrared markers on the skin and x-ray registration as the method of locating the position of the patient.	BAT can be used for the positioning of all patients that are prescribed external beam radiation treatments to organs, which are readily identifiable on ultrasound images.

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Like the predicate 2-way Foley catheter devices, the BeamCath is similar in its design configuration and material composition characteristics. The catheters are manufactured from PVC and latex materials. The catheters are designed in a similar size range. All of the devices are supplied sterile for single use.

Urological Catheter Comparison Table

Device	**BeamCath**	**Rusch Simplastic**	**Kendall Ultramer**
Catheter type	2-way Foley	2-way Foley	2-way Foley
Materials	PVC shaft and connector	PVC shaft and connector	Natural latex
	10 ml latex balloon	5 ml balloon	5 to 30 ml latex balloon
Sizes	14 FR	12 to 26 FR	12 to 24 FR
Sterile, Single Use	Yes	Yes	Yes
Intended Use	The BeamCath is a positioning device used with external beam conformal radiation therapy for visualizing the prostate position during treatment of prostate cancer. The BeamCath is introduced into the urethra as is a sterile urological catheter and is retained in place by inflating the balloon tip. Its radiopaque markers aid in radiographic visualization of the prostate position for planning, simulation and treatment of prostate cancer using dose escalation radiotherapy.	The device is intended for placement of the Foley catheter in the bladder for drainage when there is difficulty in negotiating the urethra.	The Kendall Coude Foley catheter is a urethral catheter designed with a bent tip to provide transurethral access to the obstructed bladder in the male patient for irrigation and urine drainage.

6. **Discussion of performance testing.**
Device performance tests have been conducted and successfully completed. In addition, the device has been successfully used in several clinical studies as a prostate positioning aid during dose-escalation radiotherapy.

7. **Conclusion**
Based upon performance and clinical testing and a comparison to the predicate devices, it is the conclusion of Beampoint that the BeamCath is substantially equivalent to devices already on the marked (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2005

Beampoint AB
c/o Mr. Bernard Horwath
C. G. Bundy Associates, Inc.
6740 Riverview Terrace
MINNEAPOLIS MN 55432

Re: K042110
Trade/Device Name: BeamCath®
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 EZL
Dated: February 4, 2005
Received: February 7, 2005

Dear Mr. Horwath:

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 (Premarket Approval), 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

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

Enclosure

B. INDICATIONS FOR USE

510(k) Number K042110

Device Name: BeamCath

Indications for Use:

The BeamCath is a positioning device used with external beam conformal radiation therapy for visualizing the prostate position during treatment of prostate cancer. The BeamCath is introduced into the urethra as is a sterile urological catheter and is retained in place by inflating the balloon tip. Its radiopaque markers aid in radiographic visualization of the prostate position for planning, simulation and treatment of prostate cancer using dose escalation radiotherapy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

David R. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042110