MAR 0 4 2014

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510(k) SUMMARY

seedlings
Life • Science • Ventures • LLC
230 East 15th Street, Suite 1-A
New York, NY 10003

510(k) Owner:	Seedlings Life Science Ventures
Address:	230 East 15th Street, Suite 1-A, New York, NY, 10003
Phone:	954.336.0777
FAX:	866-277-3269
Contact:	Ken Solovay, Chief Operating Officer
Email:	ken@seedlings.net
Date Prepared:	March 3, 2014
Device Trade name:	Lighthouse™ Urinary Catheter
Common name:	Urinary Catheter
Classification name:	Catheter, Retention Type, Balloon
Classification Product Code:	EZL, FGI
Regulation Number:	21 CFR 876.5130

Predicate Devices:

(1) Lighthouse Urinary Catheter

Manufacturer:	Seedlings Life Science Ventures, LLC
FDA 510(k) number:	K131655
Classification Code:	78 EZL

(2) BeamCath, Urological Catheter Patient Positioning Device

Manufacturer:	Beampoint AB
FDA 510(k) number:	K042110
Classification Code:	78 EZL

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System Description

The Lighthouse™ Urinary Catheter is a 3-lumen Foley catheter. In addition to a lumen for inflating the Foley balloon and a urine drainage lumen, the Lighthouse has a third lumen for filling 0.1cc - 1cc of air in a 4-cm length bladder along the shaft of the catheter. The Urethral Identification Bladder (UIB) has a maximum outer diameter of 24F (i.e. smaller than other urinary catheters that meet ASTM F623-99) when filled with a maximum 1cc volume described in the instructions for use (IFU) and provides echogenicity when viewed by a Transrectal Ultrasound (TRUS). The non-inflated UIB contains a narrow air space between the catheter shaft and the urethra, which provides an echogenic marker under TRUS and when necessary can be increased by adding 0.1cc – 1.0cc of volume via syringe.

Intended Use

The Lighthouse™ Urinary Catheter is intended for bladder/urinary tract drainage during prostate biopsy and brachytherapy procedures where transrectal ultrasound (TRUS) imaging is used to visualize the prostate. The catheter additionally enhances identification of the course of the posterior aspect of the prostatic urethra during TRUS-guided prostate biopsy and brachytherapy procedures by creating an acoustic interface (i.e., air) between the catheter and the urethral wall via its urethral identification bladder.

The Lighthouse is substantially equivalent to the following predicate devices: the Lighthouse Urinary Catheter (Seedlings Life Science Ventures) with its original labeling and the BeamCath Urological Catheter Positioning Device (Beampoint).

Characteristic	Lighthouse™ (Seedlings)	Lighthouse™ (Seedlings)	BeamCath (Beampoint)
510(k) number	K140099	K131655	K042110
Intended Use	The Lighthouse™ Urinary Catheter is intended for bladder/urinary tract drainage during prostate biopsy and brachytherapy procedures where transrectal ultrasound (TRUS) imaging is used to visualize the prostate. The catheter additionally enhances identification of the course of the posterior aspect of the prostatic urethra during TRUS-guided prostate biopsy and brachytherapy procedures by creating an acoustic interface (i.e., air) between the catheter and the urethral wall via its urethral identification bladder.	The Lighthouse™ Urinary Catheter is intended for bladder/urinary tract drainage during prostate brachytherapy procedures where transrectal ultrasound (TRUS) imaging is used to visualize the prostate. The catheter additionally enhances identification of the course of the posterior aspect of the prostatic urethra during TRUS-guided brachytherapy by creating an acoustic interface (i.e., air) between the catheter and the urethral wall via its urethral identification bladder.	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 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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510(k) SUMMARY

Characteristic	Lighthouse™ (Seedlings)	Lighthouse™ (Seedlings)	BeamCath (Beampoint)
510(k) number	K140099	K131655	K042110
Design	Urological catheter with Foley balloon & echogenic 24Fr air-filled bladder	Urological catheter with Foley balloon & echogenic 24Fr air-filled bladder	Urological catheter with Foley balloon & tantalum radiopaque markers
Materials	Biocompatible silicone	Biocompatible silicone	PVC shaft & latex balloon
Sterile, Patient Use	Sterile, Single-patient use	Sterile, Single-patient use	Sterile, Single-patient use
Sizes	16Fr	16Fr	14Fr

Performance The following bench tests have been performed to verify the Lighthouse performance specifications, with results demonstrating substantial equivalence:

1.) Sterilization and Shelf Life
2.) Biocompatibility
3.) Device Performance Specifications

Data

a. Visual Inspection
b. Dimensional Analysis
c. ASTM F623-99
d. Echogenicity Testing in a Phantom Model

Determination of Substantial Equivalence Based on the comparison above, the urine drainage and enhanced visualization under external imaging is equivalent to the predicate devices. The small risk of using a urinary catheter during prostate biopsy is overwhelmingly outweighed by the benefits of using the Lighthouse Catheter. The risk of urethral complication from prostate biopsy without using the Lighthouse Catheter is much greater than the risk of a complication due to use of the Lighthouse Catheter and, as such, the device does not raise new questions of safety and effectiveness.

Conclusion We believe the Lighthouse Catheter is substantially equivalent based on the indications for use and the performance testing results.

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

March 4, 2014

Seedlings Life Science Ventures
Ken Solovay
Chief Operating Officer
230 East 15th Street, Suite 1-A
New York, NY 10003

Re: K140099
Trade/Device Name: Lighthouse™ Urinary Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL, FGI
Dated: January 15, 2014
Received: January 16, 2014

Dear Ken Solovay,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k): K140099 (To be assigned)

Device Name: Lighthouse™ Urinary Catheter

Indications for Use: The Lighthouse™ Urinary Catheter is intended for bladder/urinary tract drainage during prostate biopsy and brachytherapy procedures where transrectal ultrasound (TRUS) imaging is used to visualize the prostate. The catheter additionally enhances identification of the course of the posterior aspect of the prostatic urethra during TRUS-guided prostate biopsy and brachytherapy procedures by creating an acoustic interface (i.e., air) between the catheter and the urethral wall via its urethral identification bladder.

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

Benjamin R. Fisher -S
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