2512 Artesia Boulevard Suite 305C
Redondo Beach, CA 90278
Tel: (310) 717-5822

510(k) Summary

APR 2 8 2014

Applicant: Proa Medical, Inc.
2512 Artesia Blvd. Suite 305C
Redondo Beach, CA 90278-3269
United States

Contact: Victoria Nadershahi
1-800-899-3385
victoria@proamedical.com

Date Summary Prepared: April 24th, 2014

Trade Name: Brella-Spec™ Vaginal Speculum

Common or Usual Name: Speculum, Vaginal, Nonmetal

Device Class: Class II

Classification Code: HIB

Classification Name: 21 CFR 884.4530 Speculum, Vaginal, Nonmetal.

Device Intended Use

The Brella-Spec™ Vaginal Speculum is used for visualization and exposure of the interior of the vagina by a medical professional during gynecological and obstetrical procedures and examinations.

Brella-Spec™ Vaginal Speculum provides the light necessary to illuminate the field during procedures and examinations.

Device Indications for use

The Brella-Spec™ Vaginal Speculum is used for visualization and exposure of the interior of the vagina by a medical professional during gynecological and obstetrical procedures and examinations.

Brella-Spec™ Vaginal Speculum provides the light necessary to illuminate the field during procedures and examinations.

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Predicate Device

a) Depalt Vaginal Speculum 2000 Series and Depalt Lighting System cleared for marketing under 510(k) notification number K072762.

Device Description

The Brella-Spec™ Vaginal Speculum is a sterile, single-use device with built-in LED illumination system to provide optimal visualization and access during gynecological and obstetrical procedures. This speculum was designed to provide visualization and exposure of the interior of the vagina by a medical professional during gynecological and obstetrical procedures and examinations. The device is ergonomically designed to maximize the view window using two side blades that are opened by a manually operated ratchet mechanism. The device incorporates a fully enclosed LED illumination system. It is composed of medical grade, biocompatible plastic materials.

Technological Characteristics

The Brella-Spec™ Vaginal Speculum has substantially equivalent technological characteristics and the same indications for use as the predicate device Depalt Vaginal Speculum 2000 Series and Depalt Lighting System. The use of polypropylene and acrylic polycarbonate along with providing the device in sterile PETG tray and Tyvek lid does not introduce any new concerns regarding safety or effectiveness. The design has been demonstrated as substantially equivalent using bench test data.

Performance Data

The Brella-Spec™ Vaginal Speculum has been tested for biocompatibility in accordance with the Food and Drug Administration Blue Book Memo, G95-1, use of international standard ISO-10993 Requirements for limited contact duration, surface contacting, breached mucosal membrane device and are demonstrated to be suitable for the intended use of this product. The sterilization method for the Brella-Spec™ Vaginal Speculum has been validated and tested in accordance with ISO 11137: Sterilization of healthcare products-Radiation. The packaging for the Brella-Spec™ Vaginal Speculum has been validated and tested in accordance with ISO 11607-Packaging for terminally sterile medical devices. In addition, the Brella-Spec™ Vaginal Speculum has been tested for electrically safety in accordance with IEC 60601-1, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

Verification and validation tests were conducted in accordance with Proa Medical, Inc., design control procedures. The Brella-Spec™ Vaginal Speculum was tested using established testing procedures to ensure the performance parameters conform to the product design specifications. ISO 14971- Medical Devices-Application of Risk Management to medical devices was followed to mitigate risks that may be associated with the device.

No clinical studies have been done for the purpose of obtaining safety and effectiveness data.

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Substantial Equivalence

The Brella-Spec™ Vaginal Speculum has substantially equivalent technological characteristics and the same indications for use as the predicate Depalt Vaginal Speculum 510(k) K072762. The differences in the design features do not have an impact on safety and effectiveness of the subject device.

Parameter	Subject device (K133857)	Predicate device (K072762)	Differences
Device name	Brella-Spec™ Vaginal Speculum	Depalt Vaginal Speculum and Depalt Lighting System	
Indications for Use	Same as the predicate	Used for the purposes of visualization and exposure of the interior of the vagina by a medical professional during gynecological and obstetrical procedures/ examinations. Depalt Lighting System provides the light necessary to illuminate the field during procedures/examinations."	
Dimension	• Blade (stationary) length 4.5″ • Blade (stationary) width 1.2″ • Handle length 2.5″	• Blade length 4.4″ • Blade width 1.1″ • Handle length 3″	The difference is minimal; no safety or effectiveness concerns
Blade	Triple blades (1 stationary, 2 articulating)	Dual blades (1 stationary, 1 articulating)	The difference does not have an impact on safety of the subject device. With two articulating blades, the subject device should be more effective because it provides larger vagina-contacting surface and view window.
Blade movement	2 articulating blades move horizontally	1 articulating blade moves vertically	The difference does not influence safety of subject device. The subject device should be more effective because it provides larger view window with two articulating blades.
Hinge	Same as the predicate	2-hinge system	

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Thumb paddle	1 on left side, 1 on right side	1 on back side	The difference does not cause any safety and effectiveness concerns. Actually the subject device should have better control with two thumb paddles
Ratchet teeth	Similar to the predicate	Vertical ratchet teeth	
View window	Adjustable area (5.8-31 cm^2)	Fixed area (18 cm^2)	The difference makes the subject device more flexible and effective without safety concerns
Illumination system	Same as the predicate	Built-in LED light with battery	
Materials	Polypropylene and Acrylic Polycarbonate	Polystyrene	The subject and predicate devices are different in materials. However, a full battery of biocompatibility testing was conducted on the subject device to ensure safety
Sterility	Sterile	Non-sterile	The subject device is provided sterile whereas the predicate device is not. The difference makes the subject device safer
Use life	Same as the predicate	Single-use, disposable	

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

April 28, 2014

Proa Medical, Inc.
Victoria Nadershahi
RA/QA Manager
2512 Artesia Blvd. Suite 305C
Redondo Beach, CA 90278

Re: K133857
Trade/Device Name: Brella-Spec Vaginal Speculum
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HIB
Dated: March 26, 2014
Received: March 27, 2014

Dear Victoria Nadershahi,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K133857

Device Name

Brella-Spec Vaginal Speculum

Indications for Use *(Describe)*

Brella-Spec Vaginal Speculum is used for visualization and exposure of the interior of the vagina by a medical professional during gynecological and obstetrical procedures and examinations.

Brella-Spec Vaginal Speculum provides the light necessary to illuminate the field during procedures and examinations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Benjamin R. Fisher -S
2014.04.28 14:54:22 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 number."