K092829
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Christcot Medical Company

Section 6: 510(k) Summary

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510(k) Summary Preparation Date: September 4, 2009

Proprietary Name: InsertEase™

Common Name: Rectal Suppository Applicator

Classification Name: Rectal Applicator

Device Classification: Class I

Classification Code: 876

Classification Panel: Gastroenterology and Urology

Establishment Registration Number: We do not have an establishment registration number at this time but will register within 30 days of marketing InsertEase™.

Legally marketed device to which we are claiming equivalence: The following devices are substantially equivalent predicate devices to InsertEase™ as described in the accompanying documents, which also describe the indications for use of InsertEase™.

- **Product Code: 884.4520(7) - Vaginal Applicator (common use - no singular trade name)**

  "(a)*Identification.* An obstetric-gynecologic general manual instrument is one of a group of devices used to perform simple obstetric and gynecologic manipulative functions. This generic type of device consists of the following:..."

  "(7) A vaginal applicator is an instrument used to insert medication into the vagina."

- **Product Code: 876.5210 - Enema Kit (common use - no singular trade name)**

"(a)*Identification.* An enema kit is a device intended to instill water or other fluids into the colon through a nozzle inserted into the rectum to promote evacuation of the contents of the lower colon. The device consists of a container for fluid connected to the nozzle

either directly or via tubing. This device does not include the colonic irrigation system (876.5220)."

- **Product Code: 876.5450 - Rectal Dilator (common use - no singular trade name)**

  "(a)*Identification.* A rectal dilator is a device designed to dilate the anal sphincter and canal when the size of the anal opening may interfere with its function or the passage of an examining instrument."

Device Description: The rectal suppository applicator, to be called, InsertEase™, is a plastic, non sterile, single use device for the insertion of prescription and over the counter suppositories into the rectum. The design of InsertEase™ is substantially equivalent to a vaginal applicator used for inserting vaginal suppositories, creams and tampons. One piece, the plunger, will be movably coupled within a second piece, the barrel. The barrel has an open end to receive and hold a suppository, which is then inserted into the anus. The plunger is then pushed into the barrel and places the suppository within the rectum. InsertEase™ functions in the same way and manner that vaginal applicators insert vaginal suppositories and tampons.

Indication for Use: InsertEase™ is to be used as a device for the insertion of prescription and over the counter suppositories into the rectum.

The only difference in indication of use between InsertEase™ and vaginal applicators (884.4520(7)) is the anatomical orifice of the body. InsertEase™ functions in the same way and manner that vaginal applicators insert vaginal suppositories and tampons. The difference between a vaginal suppository applicator and rectal suppository applicator is insignificant, and neither safety nor effectiveness of either device is in question when used as labeled. The alternative to both vaginal and rectal suppository applicators is the use of the finger (digital insertion), which is mimicked by both devices.

The FDA has previously addressed this difference and set precedence in the case of the Rectal Speculum (876.4730), which is deemed substantially equivalent to the vaginal speculum (884.4520(3)). Both devices are Class I devices and have the same intended use in different orifices of the body.

Technical Characteristics: Technological characteristics of InsertEase™ compared to the vaginal applicator (predicate device) are the same except for the length. The length of InsertEase™ is slightly longer than that of a vaginal applicator. InsertEase™ is a two piece plastic applicator to be extruded using medical grade plastic in an FDA approved manufacturing facility according to the Medical Device Registration and Listing requirements, which is the same as vaginal applicators currently available. The movement and function of InsertEase™ is equivalent to that of vaginal applicators.

Conclusion: The device InsertEase™ is substantially equivalent to the Substantially Equivalent Predicate Devices listed above and should be granted pre-market approval, as it will help hundreds of thousands of chronic and critically ill patients who must take rectal suppositories.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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Ms. Jennifer D. Ensign
President
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Re: K092829
Trade/Device Name: InsertEase™
Regulation Number: 21 CFR §876.4730
Regulation Name: Manual gastroenterology-urology surgical instrument and accessories
Regulatory Class: I
Product Code: OOW
Dated: September 4, 2009
Received: September 14, 2009

Dear Ms. Ensign:

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 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 5: Statement of Indications for Use

510(k) Number (if known): K092829

Device Name: InsertEase™

Indications for Use: InsertEase™ is to be used as a device for the insertion of prescription and over the counter suppositories into the rectum

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K092829