K073262

510K Summary

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MAR 2 6 2008

Device Name – Bella

Predicate Device – MammoPad

Description of Device

Bella is to be used on the bucky or the imaging receptor plate of mammography imaging equipment where the breast is placed for mammograms. The purpose of the product is to remove the cold from the bucky by placing this sheet between the patient's breast and the imaging receptor plate allowing the patient to feel more comfortable and less cold without interfering with image quality.

Bella is designed to include a non-woven fabric type material that will feel like fabric on the skin. The material is non-compressable and the sizes are to include all leading mammography equipment for small and large buckies. Bella includes printed graphics to aid in the mental comforting of the patient. There is adhesive backing to Bella which allows easy application and removal from the bucky. The material and adhesive do not affect imaging.

The product is applied directly to the bucky. The sheet itself will have a peel off backing to expose the adhesive back. The corners of the shortest ends are taken in both hands and as the mammographer moves towards the bucky, Bella is allowed to adher to the front of the bucky using this adherence as a guide to place Bella wrinkle free to the top of the bucky. After the patient's mammogram the mammographer peels Bella off the bucky and disposes of it. This is a one time use only product and the bucky does not have to be cleaned in between Bellas or in essence between patients.

Intended Use

The intended use of the product is to remove the cold from the bucky by placing this sheet between the patient's breast and the imaging receptor plate allowing the patient to feel more comfortable and less cold without interfering with image quality.

Comparison of device (Bella) to predicate device (MammoPad)

	Bella	**MammoPad K062141**
Intended use	A self adhering fabric sheet to be applied to the mammography equipment receptor plate to provide a more comfortable mammogram	A self adhering foam pad to be applied to the mammography equipment receptor plate to provide a more comfortable mammogram
Indications for use	To be applied to the mammography receptor plate, one per patient	To be applied to the mammography receptor plate, one per patient
Target population	Women over the age of 35 having mammograms	Women over the age of 35 having mammograms
Anatomical sites	Breast	Breast
Where used	Hospitals, radiology centers	Hospitals, radiology centers
Energy used and/or delivered	n/a	n/a
Human factors	Mammographers apply Bella to the mammography equipment and place women's breasts on the product	Mammographers apply MammoPad to the mammography equipment and place women's breasts on the product
Design	Rectangular in shape, white fabric, adhesive backing, pink flowers printed on white fabric	Rectangular in shape, high density foam with adhesive backing
Performance	Provides a more comfortable mammogram	Provides a more comfortable mammogram
Standards met	Remain where placed	Remain where placed
Materials	fabric, adhesive backing, ink	High density foam, adhesive backing
Biocompatibility	Fabric and FDA approved varnish on ink	Visco elastic foam
Compatibility with the environment	Disposable	disposable
Sterility	n/a	n/a
Electrical safety	n/a	n/a
Mechanical safety	n/a	n/a
Chemical safety	n/a	n/a
Thermal safety	n/a	n/a
Radiation safety	Does not image	Does not image

Substantial equivalence based on an assessment of non-clinical performance data – both products are intended to provide comfort

Substantial equivalence based on assessment of clinical performance-
Both products are considered radiolucent and do not interfere with imaging

Conclusions drawn from nonclinical and clinical tests that demonstrate the device is as safe, as effective and performs as well as or better than the predicate device

Bella

The first step in testing Bella was to develop a prototype to be tested on the mammography equipment receptor plate under the phantom, to be compared to an image with the phantom and no Bella. This test proved there were no differences in the image with Bella as compared to without.

The next step in testing was to find locations where Bella could be tested as part of a mammogram where you again compare an image with Bella and one without. The test conducted included imaging, with the patient's consent, one breast with Bella and one without. 200 tests were completed in 6 locations with again no differences between the image with Bella as compared to the image without.

The product proved to fulfill it's design intentions of removing the cold from the mammography receptor plate with it's fabric type material, making the patient more at ease with it's floral pattern and did not interfere with imaging quality.

MammoPad

BioLucent Inc., took the MammoPad to Laszlo Tabar, M.D., at Falun Central Hospital in Sweden to perform intense clinical trials. Almost 1,000 Swedish women had mammograms either with or without the MammoPad, and Tabar - could not see any adverse effects between mammograms done either way, even when examining the images with a magnifying glass. In the study, a majority of the women reported that the MammoPad cut the pain of mammography in half.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR 2 6 2008

Ms. Martine M. Boutté
New Product Development Specialist
Beekley Corporation
150 Dolphin Road
BRISTOL CT 06011

Re: K073262
Trade/Device Name: Bella
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: IZH
Dated: February 21, 2008
Received: February 21, 2008

Dear Ms. Boutté:

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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

Indications for Use

510(k) Number (if known): __K073262_____

Device Name: __Bella_____

Indications for Use:

The intended use of the product is to remove the cold from the bucky by placing this sheet between the patient's breast and the imaging receptor plate allowing the patient to feel more comfortable and less cold without interfering with image quality.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K073262