DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 15, 2016

Precision Dynamics Corporation
% Mr. Dave Yungvirt
CEO
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
MILLBURN NJ 07041

Re: K161920
Trade/Device Name: Comfort Cover
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: IZH
Dated: July 10, 2016
Received: July 13, 2016

Dear Mr. Yungvirt:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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 below.

510(k) Number *(if known)*

K161920

Device Name
Comfort Cover

Indications for Use *(Describe)*

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

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)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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27770 N. Entertainment Dr.
Ste. 200
Valencia, CA 91355
800.847.0670
818.897.1111
Email info@pdcorp.com

pdcorp.com

SECTION 5: 510(k) SUMMARY

The following information is provided in accordance with 21 CFR 807.92, for the Traditional Premarket 510(k) Summary:

(1) SUBMITTER INFORMATION

Company Name and Address:	Precision Dynamics Corporation (PDC) 27770 N. Entertainment Drive, Suite 200, Valencia, California, 91355
Contact Name:	Swarna Mukund Ph. D.
Contact Telephone:	(661) 481-8857
Contact E-mail:	swarna_mukund@bradycorp.com
Date Prepared:	June 10, 2016

(2) DEVICE INFORMATION

Trade Name:	Comfort Cover™
Name of Device:	Comfort Cover
Common Name:	Mammography Cover
Classification Name:	System, X-ray, mammographic
Regulatory Classification:	Class II
Regulation Number:	892.1710
Product Code:	IZH

(3) PREDICATE DEVICE

K073262, Bella, Bella Blankets:	Beekley Corporation
Classification Name:	System, X-ray, mammographic
Regulatory Classification:	Class II
Regulation Number:	892.1710
Product Code:	IZH

(4) DEVICE DESCRIPTION

Comfort Cover is a single-use disposable cover placed between the patient's breast and the image receptor plate during mammography. The purpose of this product is to allow the patient to feel more comfortable and less cold during the mammographic examination without interfering with image quality. Comfort Cover will allow for artifact-free images in both Full Field Digital Mammography (FFDM) and Digital Breast Tomosynthesis (DBT), patient radiation dose is equivalent to that when using no Comfort Cover and the Image quality is equivalent to images exposed without Comfort Cover.

Comfort Cover is designed to fit small and large image receptor plates of all leading mammographic equipments. The product is constructed of a fabric material with a purple printed design and has adhesive backing with a paper liner. Both the material and adhesive backing of the product do not affect imaging.

The product is directly applied wrinkle free to the top of the image receptor plate of the mammographic machine by the adhesive backing exposed by peeling off the liner. After the patient's mammogram, the product is peeled off the image receptor plate and disposed. As the product removes cleanly without leaving behind any residue, the image receptor plate does not need to be cleaned between Comfort Covers nor between patients.

(5) INDICATIONS FOR USE

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

(6) COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table compares the Comfort Cover to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5-1: Comparison of Technological Characteristics with Predicate Device

Device Characteristics	Comfort Cover	Bella	Significant Differences
Indications for Use	The indications for use of the product is to remove the cold from the bucky by placing this sheet between patient's breast and the imaging receptor plate allowing the patient to feel more comfortable and less cold without interfering with image quality.	The intended use of the product is to remove the cold from the bucky by placing this sheet between patient's breast and the imaging receptor plate allowing the patient to feel more comfortable and less cold without interfering with image quality.	None
Target population	Women over the age of 35 having mammograms.	Women over the age of 35 having mammograms	None
Where used	Hospitals, radiology centers	Hospitals, radiology centers	None
Product Size	22.9cm x 27.9cm designed for use with 18cm x 24cm image receptor plate 29.2cm x 33.0cm designed for use with 24cm x 30cm image receptor plate	22.9cm x 27.9cm designed for use with 18cm x 24cm image receptor plate 29.2cm x 33.0cm designed for use with 24cm x 30cm image receptor plate	None
Material	Fabric (woven), adhesive backing, purple ink.	Fabric (non-woven), adhesive backing, pink ink.	Different. Safety and performance testing results have shown that the slight differences in material composition do not affect safety and effectiveness.

Device Characteristics	Comfort Cover	Bella	Significant Differences
Packaging and Labeling	Not individually wrapped. Fifty covers packaged in one box of Comfort cover.	Not individually wrapped. Fifty covers packaged in one box of Comfort cover.	None
	Prescription use only.	Prescription use only.	None
	Labeling same as Bella.	NA	NA
Biocompatibility	Yes	Yes	None
Performance Testing	No visible defects.	No visible defects.	None
	Repositionable Adhesive	Repositionable Adhesive	None
	Provides comfort and removes cold during a mammographic examination without affecting quality of the images.	Provides comfort and removes cold during a mammographic examination without affecting quality of the images.	None
	Allows for artifact-free images and image quality equivalent to images exposed without Comfort Cover.	Not tested side-by-side with Comfort Cover. Bella testing results can be found in their 510k (K073262).	None
	Removes cleanly from the mammographic equipment without leaving behind any residue.	Removes cleanly from the mammographic equipment without leaving behind any residue.	None
	Printed ink does not smear.	Printed ink does not smear.	None
	Remains where placed.	Remains where placed.	None
Sterility	Non-sterile	Non-sterile	None
Dispensing method	Dispenser Box	Dispenser Box	None
Environment Compatibility	Disposable, Non-recyclable	Disposable, Non-recyclable	None
Radiation Safety	Does not image, no artifacts, quality of images not affected, radiolucent.	Not tested side by side with Comfort Cover. Bella testing results can be found in their 510k (K073262).	None

(7) PERFORMANCE DATA

As part of demonstrating safety and effectiveness of Comfort Cover and in showing substantial equivalence to the predicate device, Precision Dynamics Corporation completed a number of non-clinical performance tests. The Comfort Cover met all the requirements for overall design, biocompatibility, and radiologic safety confirming that the design output meets the design inputs and specifications for the device.

Summary and Conclusions of Biocompatibility Testing

Biocompatibility testing was conducted in accordance *with ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro Cytotoxicity*; and *ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*.

The subject device passed all of the above tests.

Summary and Conclusions of Comparative Testing
The following mechanical tests were conducted on both the subject and the predicate devices.

- Visual and Dimensional examination
- Thermal Conductivity Test
    - This testing was performed per ASTM D5470-12 which is a test method for measurement of thermal conductivity of materials.
- Ink Smear Test
    - This test was performed as per ASTM D5264-98 which is a standard test method for abrasion resistance of printed materials by the Sutherland Rub Tester to test if the ink from the printed graphics smears.
- Peel Adhesion Test
    - This test was performed as per ASTM D6252-98 which is a standard test method for peel adhesion of pressure sensitive label Stocks at a 90° Angle to test the peel adhesion of the device.
- Removes Cleanly Test
    - This test was an in-house developed method to test if the product removes cleanly from the mammographic equipment without leaving behind any residue.

The subject device passed all of the above tests.

Summary and Conclusions of Radiological Studies
Phantom image testing was performed as per MQSA regulations and with relevant International Electro technical Commission (IEC) standards (62220-1-2:2007 and 61223-3-2) to verify that,

- Comfort Cover will allow for artifact-free images in both FFDM and DBT.
- Patient radiation dose is equivalent to that when using no Comfort Cover.
- Image quality is equivalent to images exposed when using no Comfort Cover.

The subject device passed all of the above tests.

Summary and Conclusions of Usability Studies
Usability studies included radiologists, radiology technologists and patients testing all of the user need requirements. The Comfort Cover fulfilled its design requirements of making the mammography examination more comfortable and did not negatively impact patient positioning.

Summary of Animal Studies
No animal testing was necessary.

Summary of Clinical Studies
No clinical testing was necessary.

8) CONCLUSIONS

The subject device Comfort Cover and the predicate device Bella have the same technological characteristics and intended use.

Both devices have similar design of having rectangular shape with adhesive backing which allows easy application and removal from the image receptor plate and with floral graphics printed on the top of the sheet using FDA approved ink. Both devices are presented as single use, non-sterile and non-compressible.

Both devices remove the cold from the image receptor plate of the mammographic equipment and provide comfort during routine mammographic examinations without affecting image quality. Both devices do not negatively affect patient positioning.

Minor difference in the Comfort Cover material as compared to the predicate device, Bella does not affect safety and effectiveness of the device when used as labeled as shown by safety and efficacy studies. Therefore, Precision Dynamics Corporation believes that Comfort Cover is substantially equivalent to the existing legally marketed predicate device, Bella.