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

BCG Medical, LLC
Ms. Lisa Giap
Director of Operations
6715 Rancho Toyon Place
San Diego, California 92130

Re: K162562
Trade/Device Name: Opt-Shield™ AIR Supine, Opt-Shield™ AIR Lithotomy
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: December 19, 2016
Received: December 19, 2016

Dear Ms. Giap:

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,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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 below.*

510(k) Number *(if known)*
K162562

Device Name
Opt-Shield AIR Supine, Opt-Shield AIR Lithotomy

Indications for Use *(Describe)*
The Opt-Shield AIR Convection Warming technology is intended to prevent and treat hypothermia. In addition, the temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patient to become too cold.

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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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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# Traditional 510(k) Submission Summary, K162562

**DATE PREPARED:** September 6th, 2016
**DATE REVISED**: March 6th, 2016

**GENERAL INFORMATION**

Applicant's Name: BCG Medical, LLC
Address: 6715 Rancho Toyon place
San Diego, CA 92130
Website: www.bcgmedical.com
Phone: 858-349-1331
Fax: 858-869-0899
Registration Number: 27-3718418
Contact Person: Lisa Giap
Email: Lisa@bcgmedical.com

**Device names**:
Trade Name: 1) Opt-Shield™ AIR Supine (Proposed device)
2) Opt-Shield™ AIR Lithotomy (Proposed device)
Common/Usual Name: Convective Warming Blanket

Regulation Number: 21 CFR 870.5900
Classification Name: Thermal Regulating System (21CFR 870.5900, Product Code DWJ)

**Reason for the 510(k):** BCG Medical has added an additional function, the Convective Warming Function, a class 2 classification, to our currently class 1 marketed device, the Opt-Shield Supine and Opt-Shield Lithotomy.

**Predicate:** 3M Bair Hugger™ Temperature Management Blanket, Full Access Underbody, model 635 (Predicate K001149)

**Proposed** Opt-Shield AIR comprises of the following devices: (Trade Names)

1) Opt-Shield™ AIR Supine (blue and white)
2) Opt-Shield™ AIR Lithotomy (blue and white)

**Device description**:

Predicate:

3M Bair Hugger, Temperature Management Blanket, Full Access Under body, model 635 (Predicate K001149). It is made of two layers of non- woven laminated tissue fabric. The layers are glued (or bonded) together to form a network of air channels. The warm air circulates within blanket and delivers warm air around the patient's body through perforations in the patient side layer of the blanket. The distribution of air is designed to equally deliver air at the similar temperature air at various blanket locations. The model 635 comes with two (2) hose ports for receiving warm air.

Proposed device:

Opt-Shield™ AIR, SAFE Patient-Handling System for Surgical Patient:

The proposed Opt-Shield AIR blanket consists of three layers of material: bottom layer nylon impermeable to air (non-contact), middle layer plastic with predetermined holes (non-contact), and top layer polypropylene (in contact with the patient) with microscopic holes (intrinsic to the fabric) throughout the fabric. The three layers are sewn together to create air channels to allow air distribution evenly throughout the blanket to minimize heat reduction. The warm air circulates within blanket and delivers warm air around the patient's body through perforations in the patient side layer of the blanket. The distribution of air is designed to equally deliver air at the similar temperature air at various blanket locations. It has one hose port for receiving warm air.

**Indications for Use:**

The Opt-Shield AIR Convection Warming technology is intended to prevent and treat hypothermia. In addition, the temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patient to become too cold.

**Technological characteristics:**

Predicate: Two layers of non-woven laminated tissue fabric, polypropylene and polyethylene, network of channels created by heat sealing to allow even heat distribution

throughout the blanket. It has two air inlets.
Proposed Opt-Shield AIR: Two layers of non-woven laminated tissue fabric, polypropylene and polyethylene **plus** a third layer of nylon fabric that is not in contact with the patient, and network of channels created by sewing the three layers to allow even heat distribution throughout the blanket. It has one air inlet.

**Summary of the main non-clinical test results:**
The purpose of this internal testing is to compare the effectiveness of heat distribution performances inside and on the surface, internal airflow performances, pressure performances and durability performances of the convective warming blanket of the Opt-Shield AIR (OSA) by BCG Medical in comparison to the Bair Hugger (BH) Full Access Underbody Blanket (Predicate) using the same heat source, the Bair Hugger/3M Warming Unit Model 775.
In addition, each of the Opt-Shield AIR samples were also tested for durability and integrity for at least 8 hours continuously with the warming unit running at highest heat setting (43 degree C). They were then carefully inspected for any damages. All the sealed lines and the fabric integrity were completely intact after the 8 hours of Test of Durability and Integrity.

**Finding summary**: Surface temperatures, Internal temperatures, Internal Airflows and Internal pressures are substantially similar. We concluded that the Opt-Shield AIR convective warming blanket is **substantially equivalent** to Bair Hugger Full Access Underbody blanket in performance in terms of surface temperature, internal temperature, internal airflow, internal pressure and durability.

**Conclusion:**
The Opt-Shield AIR is classified as class II and is substantially equivalent to the predicate device, the 3M Bair Hugger Temperature Management System, Full Access Underbody blanket (Predicate K001149), based on comparisons of the device classifications, intended use, and technological characteristics.