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

March 4, 2015

Cardinal Health 200, LLC
Ms. Lavenia Ford
Manager, Regulatory Affairs
1500 Waukegan Road
Waukegan, Illinois 60085

Re: K142990
Trade/Device Name: Cardinal Health Insta-Gard® Surgical and Procedure Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 4, 2015
Received: February 5, 2015

Dear Ms. Ford:

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" (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 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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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)*
K142990

Device Name
Cardinal Health Insta-Gard® surgical and procedure masks

Indications for Use *(Describe)*
Cardinal Health Insta-Gard® surgical and procedure mask is intended to be worn by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and airborne particulates. The Cardinal Health Insta-Gard® surgical and procedure masks are single use, disposable devices provided non-sterile.

This submission covers 15 catalog numbers of Insta-Gard® surgical and procedure masks models, see Table 1 below. Each model is a three-layer mask of varying composition and has been tested according to ASTM F2100-11 Standard Specification for Performance of Materials Used in Medical Face Masks and meets Level 1 criteria.

Table 1: Product Description and Catalog Number

Catalog # Description, Color

AT771145 Insta-Gard® surgical mask Ties Dancing Bandages Print
AT71235 Insta-Gard® surgical mask Anti-fog foam strip, and tiesBlue
AT71035 Insta-Gard® surgical mask ties Blue
AT71039 Insta-Gard® surgical mask Horizontal ties Blue
AT73035Insta-Gard® surgical maskTiesWhite
AT752007 Insta-Gard® surgical mask Anti-fog foam strip, vapor barrier, and ties Green
AT752005 Insta-Gard® surgical mask Anti-fog foam strip, vapor barrier, and ties Green
AT73835 Insta-Gard® surgical mask Anti-fog foam strip, and ties Green
AT72835 Insta-Gard® surgical mask Anti-fog foam strip, and ties Green
AT7505P Insta-Gard® surgical mask Ties Blue
AT73335 Insta-Gard® surgical mask Ties White
AT71021 Insta-Gard® procedure mask Earloops Blue
AT70021 Insta-Gard® procedure mask Earloops Yellow
AT7511-WE Insta-Gard® procedure mask Eye shield, anti-fog foam strip, and earloops Blue
AT771141 Insta-Gard® procedure mask Earloops Dancing Bandages Print

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.

1500 Waukegan Road
Waukegan, IL 60085

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510(k) SUMMARY
Insta-Gard® Surgical and Procedure Masks

Manufacturer:	Cardinal Health 200, LLC 1500 Waukegan Road Waukegan, IL 60085
Regulatory Affairs Contact:	Lavenia Ford 1500 Waukegan Road Waukegan, IL 60085
Telephone Number:	(847) 887-3323
Fax Number:	(847) 785-2461
Date summary Prepared:	December 31, 2014
Trade Name:	Insta-Gard® Surgical Mask Insta-Gard® Procedure Mask
Regulation Number/Device Class:	Class II per 21 CFR § 878.4040
Regulation Name:	Surgical Apparel
Common Name:	Surgical Mask Procedure Mask
Product Code:	FXX
Predicate Device:	K110455 –Kimberly-Clark, KC100 Face Mask(s)

Description

The Cardinal Health Insta-Gard® surgical and procedure masks are identified by Regulation 21 CFR 878.4040 with product code FXX.

The Cardinal Health Insta-Gard® surgical and procedure masks are constructed of varying materials (**see Table 3**). The three layers of the mask body are collated and sonically welded around the edges to enclose the filter media. The mask is provided with nonwoven polyolefin ties or polyester-spandex earloops (both attached by ultrasonic welding). A malleable nosepiece is placed within the binding for comfort and individualized fit around the wearer's nose. The surgical masks will be provided with or without an eye shield. Cardinal Health surgical and procedure masks are a single use, disposable device provided non-sterile.

Indications for Use

Cardinal Health Insta-Gard® surgical and procedure masks are intended to be worn by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and airborne particulates. The Cardinal Health Insta-Gard® surgical and procedure masks are single use, disposable devices provided non-sterile.

This submission covers 15 catalog numbers of Insta-Gard® surgical and procedure masks models, see **Table 1** below. Each model is a three-layer mask of varying composition and has been tested according to ASTM F2100-11 Standard Specification for Performance of Materials Used in Medical Face Masks and meets Level 1 criteria.

Table 1: Product Description and Catalog Number

Catalog #	Trade Name	Design Features	Color
AT771145	Insta-Gard® surgical mask	Ties	Dancing Bandages Print
AT71235	Insta-Gard® surgical mask	Anti-fog foam strip, and ties	Blue
AT71035	Insta-Gard® surgical mask	ties	Blue
AT71039	Insta-Gard® surgical mask	Horizontal ties	Blue
AT73035	Insta-Gard® surgical mask	Ties	White
AT752007	Insta-Gard® surgical mask	Anti-fog foam strip, vapor barrier, and ties	Green
AT752005	Insta-Gard® surgical mask	Anti-fog foam strip, vapor barrier, and ties	Green
AT73835	Insta-Gard® surgical mask	Anti-fog foam strip, and ties	Green
AT72835	Insta-Gard® surgical mask	Anti-fog foam strip, and ties	Green
AT7505P	Insta-Gard® surgical mask	Ties	Blue
AT73335	Insta-Gard® surgical mask	Ties	White
AT71021	Insta-Gard® procedure mask	Earloops	Blue
AT70021	Insta-Gard® procedure mask	Earloops	Yellow
AT7511-WE	Insta-Gard® procedure mask	Eye shield, anti-fog foam strip, and earloops	Blue
AT771141	Insta-Gard® procedure mask	Earloops	Dancing Bandages Print

Device and Predicate Device Technical Characteristics

The Cardinal Health Insta-Gard® surgical and procedure masks are substantially equivalent to the Kimberly Clark surgical and procedure mask with regards to claims, safety and effectiveness, design, technology, and intended use. See **Table 4** below.

Table 4: Comparison of Predicate device and Cardinal Health Insta-Gard® Surgical and Procedure Masks

Element of Comparison	Kimberly-Clark (KC100)	Cardinal Health Insta-Gard® Surgical and Procedure Masks
Intended Use	The Kimberly Clark KC100 Face Mask(s) is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The Kimberly Clark KC100 face mask(s) is a single use, disposable device(s), provided non-sterile.	**Insta-Gard® Surgical Mask** Cardinal Health Insta-Gard® surgical masks are intended to be worn by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and airborne particulates. The Cardinal Health Insta-Gard® surgical masks are single use, disposable devices provided non-sterile. **Insta-Gard® Procedure Mask** Cardinal Health Insta-Gard® procedure masks are intended to be worn by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and airborne particulates. The Cardinal Health Insta-Gard® procedure masks are single use, disposable devices provided non-sterile
Material Composition	3 layer mask made from nonwoven polyester blends, tissue, cellulose, and polypropylene materials	**Insta-Gard® Surgical Mask** 3 layer mask made from nonwoven tissue, cellulose, and polyolefin materials **Insta-Gard® Procedure Mask** 3 layer mask made from nonwoven tissue, cellulose, and polyolefin materials
Specifications and Dimensions	**KC100 Surgical Mask** 6.875"x3.75" **KC100 Procedure Mask** 6.9"x4.5"	**Insta-Gard® Surgical Mask** AT771145 – 7"x4" AT71235 – 7"x4" AT71035 – 7"x4" AT71039 – 7.5"x7.5" AT73035 – 7"x4"

		AT752007 – 7"x4" AT752005 – 7"x4" AT73835 – 7"x4" AT72835 – 7"x4" AT7505P – 7"x4" AT73335 – 7"x4" **Insta-Gard® Procedure Mask** AT7511-WE – 7"x3.375" AT771141 – 7"x3.375" AT71021 – 7"x3.375" AT70021 – 7"x3.375" See **Appendix I** for mask specifications
Mask Style	Pleated	**Insta-Gard® Surgical Mask** Pleated **Insta-Gard® Procedure Mask** Pleated
Design Features	**KC100 Surgical Mask** Fog-Free **KC100 Procedure Mask** Fog-Free	**Insta-Gard® Surgical Mask** AT771145 – Ties AT71235 – Anti-fog foam strip and Ties AT71035 – Ties AT71039 – Horizontal Ties AT73035 – Ties AT752007 – Anti-fog foam strip, Vapor barrier, and Ties AT752005 – Anti-fog foam strip, Vapor barrier, and Ties AT73835 – Anti-fog foam strip and Ties AT72835 – Anti-fog foam strip and Ties AT7505P – Ties AT73335 – Ties **Insta-Gard® Procedure Mask** AT7511-WE – Eye shield, Anti-foam fog strip, and Earloops AT771141 – Earloops AT71021 – Earloops AT70021 – Earloops
Physical Testing	Predicate device was tested according to ASTM F2100-11 Level 1 in previous 510(k) submission K110455.	**Insta-Gard® Surgical Mask** Device was tested in accordance with ASTM F2100-11, and meets Level 1 requirements. **Insta-Gard® Procedure Mask** Device was tested in accordance with ASTM F2100-11, and meets Level 1 requirements.

All results of testing met ASTM F2100-11 Level 1 acceptance criteria. ASTM F2100-11 Level 1 was performed at an AQL of 4% (32 samples tested, accept on 3 failures and reject on 4 failures).

Conclusion Statement

The Insta-Gard® surgical and procedure masks are substantially equivalent to the predicate device, in terms of general intended use performance testing, material composition, configurations/dimensions, and safety and effectiveness.