Cardinal Health 200, LLC
Dominic Tunzi
Regulatory Affairs Manager
3651 Birchwood Drive
Waukegan, Illinois 60085

Re: K192374
Trade/Device Name: Cardinal Health Level 3 Surgical Mask with Anti-Fog Foam Strip
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 29, 2019
Received: August 30, 2019

Dear Dominic Tunzi:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Elizabeth Claverie, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192374

Device Name
Cardinal Health™ Level 3 Surgical Mask with Anti-Fog Foam Strip

Indications for Use *(Describe)*
The Cardinal Health™ Level 3 surgical masks with Anti-Fog Foam Strip 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™ Level 3 surgical masks are single use, disposable devices provided non-sterile.

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.

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3651 Birchwood Drive
Waukegan, IL 60085
www.cardinalhealth.com

510(k) SUMMARY
Cardinal Health™ Level 3 Surgical Mask with Anti-Fog Foam Strip
K192374

Manufacturer:	Cardinal Health 200, LLC 3651 Birchwood Drive Waukegan, IL 60085
Regulatory Affairs Contact:	Dominic Tunzi 300 South Riverside Plaza Suite 2010 Chicago, IL 60606
Telephone Number:	(312) 270-2172
Fax Number:	(312) 775-9324
Date Summary Prepared:	Nov 22, 2019
Trade Name:	Cardinal Health™ Level 3 Surgical Mask with Anti-Fog Foam Strip
Regulation Number:	21 CFR §878.4040
Device Class:	Class II
Regulation Name:	Surgical Apparel
Common/Classification Name:	Surgical Mask
Product Code:	FXX
Predicate Device:	Cardinal Health™ Level 3 Surgical Mask with Anti-Fog Foam Strip (Catalog # AT74535; K140155)

Description

The Cardinal Health™ Level 3 Surgical Mask with Anti-Fog Foam Strip is a Class II medical device under Regulation 21 CFR 878.4040, Surgical apparel and the FDA product code of FXX. The device description of the Cardinal Health™ Level 3 Surgical Mask with Anti-Fog Foam Strip is in accordance with the *Guidance on Surgical Masks - Premarket Notification [510(k)] Submissions*, issued on March 5, 2004.

The Cardinal Health™ Level 3 Surgical Mask with Anti-Fog Foam Strip is a four-layer mask constructed of 1 layer of nonwoven polyester/polyethylene blend (inner facing), 1 layer of nonwoven polyolefin melt blown (filter media), 1 layer of nonwoven polyester/polyethylene blend (middle layer), and 1 layer polyolefin spunbond material (outer facing). The four 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 attached by ultrasonic welding. A malleable nosepiece is placed within the binding for comfort and individualized fit around the wearer's nose. The Anti-Fog Foam Strip is intended to minimize fogging.

This submission is for one (1) surgical mask model:

Catalog Number: AT73635
Description: Surgical Mask with Anti-Fog Foam Strip
Color: White

Indications for Use/Intended Use

Cardinal Health™ Level 3 Surgical Masks with Anti-Fog Foam Strip 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™ Level 3 surgical masks are single use, disposable devices provided non-sterile.

Technical Characteristics

Table 5.1

Comparison of Predicate and Proposed devices

Element of Comparison	**Predicate Device (K140155):** Cardinal Health™ Level 3 Surgical Mask with Anti-Fog Foam Strip	**Subject Device (K192374):** Cardinal Health™ Level 3 Surgical Mask with Anti-Fog Foam Strip	**Comparison**
Intended Use	Cardinal Health™ Level 3 Surgical Masks with Anti-Fog Foam Strip 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™ Level 3 surgical masks are single use, disposable devices provided non-sterile.	Cardinal Health™ Level Surgical Masks with Anti-Fog Foam Strip 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™ Level 3 surgical masks are single use, disposable devices provided non-sterile.	Identical
Material Composition	Four-layer mask constructed of: 1 layer of nonwoven cellulose (inner facing) 1 layer of nonwoven polyolefin melt blown (filter media) 1 layer of nonwoven polyester/polyethylene blend (middle layer) 1 layer of polyolefin spunbond material (outer facing)	Four-layer mask constructed of 1 layer of nonwoven polyester/polyethylene blend (inner facing) 1 layer of nonwoven polyolefin melt blown (filter media) 1 layer of nonwoven polyester/polyethylene blend (middle layer) 1 layer of polyolefin spunbond material (outer facing)	Similar
Dimensions	7 inches x 4 inches	7 inches x 4 inches	Identical
Mask Style	Pleated	Pleated	Identical
Design Features	Blue Anti-fog foam strip, ties and malleable nosepiece	White Anti-fog foam strip, ties and malleable nosepiece	Similar
Sterility	Non-Sterile	Non-Sterile	Identifcal
Use	Single Use; Disposable	Single Use; Disposable	Identical
Color	Multicolor	White	Different
Biocompatibility	The predicate device was tested in accordance with ISO 10993 and passed acceptance criteria.	The Cardinal Health™ Level 3 Surgical Mask with Anti-Fog Foam Strip was tested in accordance with ISO 10993 and passed acceptance criteria.	Similar

Summary of Nonclinical Testing

The Cardinal Health™ Level 3 Surgical Masks with Anti-Fog Foam Strip have been tested according to ASTM 2100-11 and standards which comprise ASTM F2100-11, Standard Specification for Performance of Materials Used in Medical Face Masks. See Table 5.2 for a testing summary.

Table 5.2

Summary of ASTM F2100-11 Testing

Test	Purpose	Acceptance Criteria per ASTM F2100-11 Level 3 (AQL = 4.0%)	Subject Device Test Results	
			Test Results ASTM F2100-11 Level 3	Average
ASTM F1862 Synthetic Blood	Determine synthetic blood penetration resistance	160 mmHg	Pass (31/32)	N/A
ASTM F2101 BFE	Determine the bacterial filtration efficiency	≥ 98%	Pass (32/32)	99.7%
ASTM F2299 PFE at 0.1 micron	Determine sub-micron particulate filtration efficiency	≥ 98%	Pass (32/32)	99.2%
Mil-M-36954C Delta P	Determine breathing resistance or differential pressure	< 5.0 mm H_2O/cm^2	Pass (32/32)	2.8 mm H_20/cm^2
CPSC 1610 Flammability	Determine flammability or flame spread	Class 1	Pass (32/32)	Did Not Ignite

All results of testing met ASTM F2100-11 Level 3 acceptance criteria.

Conclusion Summary

The conclusions drawn from the nonclinical tests demonstrate that the subject Cardinal Health™ Level 3 Surgical Mask with Anti-Fog Foam Strip is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K140155.