DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 24, 2015

Halyard Health, Inc.
Mr. Roberto F. Refeca
Associate Director, Regulatory Affairs
5405 Windward Parkway
Alpharetta, GA 30004

Re: K143287
Trade/Device Name: FLUIDSHIELD* Surgical Mask with Expanded Chamber
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 24, 2015
Received: February 25, 2015

Dear Mr. Refeca,

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,

Tejashri Purohit-Sheth, M.D.

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

Erin Keith
Director
Division of Anesthesiology,
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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)*
K143287

Device Name
FLUIDSHIELD* Surgical Mask with Expanded Chamber

Indications for Use *(Describe)*
The Expanded Chamber Surgical Face Mask 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 to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

39123 Expanded Chamber Surgical Face Masks w/o Visor
39124 Expanded Chamber Surgical Face Mask with Visor

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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Halyard Health, 510K Summary per the requirements of SMDA 1990 and 21 CFR 807.92

510K Owner/ Application	Halyard Health, Inc. 5405 Windward Parkway Alpharetta, GA 30004
Contact Person	Roberto F. Refeca Associate Director, Regulatory Affairs Tel: 470.448.5586 Fax: 678.254.0104 Roberto.refeca@hyh.com
Date Prepared	03-24-2015
Trade Name	FLUIDSHIELD* Surgical Mask with Expanded Chamber
Common Name	Surgical mask
Classification Name	Surgical mask
Review Panel	General and Plastic Surgery
Device Classification and Product Code	Class II per 21 CFR §878.4040 Product Code – FXX

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Halyard Health, 510K Summary per the requirements of SMDA 1990 and 21 CFR 807.92, Continued

Predicate Device

The Halyard FLUIDSHIELD Surgical Mask with Expanded Chamber, the subject of this submission, is substantially equivalent to the Kimberly-Clark Level 2 face masks originally cleared in K111402.

Component	**Predicate Device KC200 & 300 Surgical Mask (K111402)**		**FLUIDSHIELD* Surgical Mask with Expanded Chamber (Proposed Device)**
	KC200	**KC300**	
Intended Use	The Kimberly-Clark, KC200 and KC300 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, KC200 and KC300 face mask(s) is a single use, disposable device(s), provided non-sterile. Same		Same: The Expanded Chamber Surgical Face Mask 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 to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.
Mask Design	Flat Pleated		Expanded Chamber (Duckbill)
Sterile	Non Sterile		Non Sterile
Single Use	Yes		Yes
Outer Facing	Polyester Cellulose (Blue/Orange Print)	Orange Polypropylene Spunbond	Top Half: Blue Polypropylene Spunbond (w Print) Bottom Half: White Polypropylene Spunbond
Spunbond Middle Layer	Polypropylene Spunbond		Polypropylene Spunbond
Meltblown Middle Layer	Polypropylene Meltblown		Polypropylene Meltblown
Inner Facing Layer	Polyester Cellulose		Polyethylene/Polyester

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Component	Predicate Device KC200 & 300 (K111402)		FLUIDSHIELD* Surgical Mask with Expanded Chamber (Proposed Device)
	KC200	KC300	
Top and Bottom Binding	Polyester Spunlace or Polypropylene Spunbond		Polypropylene Spunbond
Ties	Polyester Spunlace		Polyester Spunlace or Polypropylene Spunbond
Branding	Kimberly-Clark, Markem Ink, Blue		Halyard Branding (Colorant not used, embossed logo)
Style	Flat-pleated		Expanded Chamber
Offered with Visor	Yes		Yes
Product Performance Specifications	Meets ASTM F2100-11, ASTM F1862-07, ASTM F2101-07, ASTM F2299-03, MIL-M369454C 16 CFR 1610 (PSC CS-191-53) ASTM Level 2 Performance (KC200)	Meets ASTM F2100-11, ASTM F1862-07, ASTM F2101-07, ASTM F2299-03, MIL-M369454C 16 CFR 1610 (PSC CS-191-53) ASTM Level 3 Performance (KC300)	Meets ASTM F2100-11, ASTM F1862-07, ASTM F2101-07, ASTM F2299-03, MIL-M369454C 16 CFR 1610 (PSC CS-191-53) ASTM Level 2 Performance (KC200)
Biocompatibility	Biocompatible, Non-cytotoxic, Non-sensitizing, Non-irritating		Biocompatible, Non-cytotoxic, Non-sensitizing, Non-irritating
Dimensions Width (Cheek to Cheek)	6.5” ± 0.75”	6.5” ± 0.75”	7.5” ± 0.11”
Dimensions Length (Nose to Chin)	4” ± 0.75”	4” ± 0.75”	8.3” ± 0.4”

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Halyard Health, 510K Summary per the requirements of SMDA 1990 and 21 CFR 807.92, Continued

Device Description	The product is a face mask utilizing an expanded chamber design consisting of nonwoven spunbond, nonwoven meltblown, and nonwoven inside layer material, nosepiece, and nonwoven ties and may be produced with or without a visor.
Intended Use	The Expanded Chamber Surgical Face Mask 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 to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.
Model Numbers	39123 Expanded Chamber Surgical Face Mask (w/o Visor) 39124 Expanded Chamber Surgical Face Mask (with Visor)
Technological Characteristics	There FLUIDSHIELD* Surgical Mask with Expanded Chamber is substantially equivalent to the current ASTM F2100-11 Level 2 Surgical Mask (K111402), the product conforms with ASTM 2100-11 and the Guidance for Industry and FDA Staff: *Surgical Masks-Premarket Notification 510K Submissions, issued March 5, 2004*.

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Performance Testing

The **FLUIDSHIELD* Surgical Mask with Expanded Chamber** has been tested according to ASTM 2100-11, and meets the requirements for a Level 2 designation:

Performance Characteristic, Level II per ASTM F2100	**Applicable Testing and/or Referenced Standard (Method)**	**FLUIDSHIELD* Surgical Mask with Expanded Chamber**
Differential Pressure mm $H2O/cm^2$	MIL-M-36954C	Met Acceptance Criteria
PFE- Particulate Filtration	ASTM F2299	Met Acceptance Criteria
BFE-Bacterial Filtration	ASTM F2101	Met Acceptance Criteria
Flammability	16 CFR Part 1610	Met Acceptance Criteria
Fluid Resistance, synthetic blood	ASTM F1862	Met Acceptance Criteria
Biocompatibility (Mask and Visor)	ISO 10993	Met Acceptance Criteria

Summary of Test Results and Conclusion

All safety and performance testing conducted met the acceptance criteria.

The conclusions drawn from the non-clinical tests demonstrate that the device is substantially equivalent to the predicate device, K111402.