K100846

AUG 16 2010

510(K) SUMMARY

Trade Name:	IMC Surgical Face Mask (non-sterile and sterile, yellow)
Common Name:	Surgical Face Mask
Classification Name:	21 CFR 878.4040 (b): Surgical Apparel
Submitter Information:	International Medsurg Connection 935 N Plum Grove Rd, STE F Schaumburg, Illinois 60173
Summary Prepared By:	Peter Kim Quality Manager International Medsurg Connection 935 N Plum Grove Rd, STE F Schaumburg, Illinois 60173 Telephone: 847-619-9926 Fax: 847-619-9927 e-mail: peterkim@intlmedsurg.com
Date Prepared:	June 7, 2010
Predicate Devices:	• Medline Prohibit Series Surgical Mask With Fluid Shield (K991559) • Crosstex Isolite Earloop Face Masks-Blue, Pink, Crosstex Isofluid Earloop Face Masks-Blue, Pink, White, Green (K012602)

Device Name(s):

IMC Surgical Face Mask (non-sterile and sterile, yellow)

Classification Panel:

General and Plastic Surgery

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed:

International Medsurg Connections, Inc is claiming substantial equivalence of the IMC Surgical Mask with the currently marketed:

Description	510(k) Number	Clearance Date
Medline Prohibit Series Surgical Mask With Fluid Shield	K991559	08/23/1999
Crosstex Isolite Earloop, Crosstex Isofluid Earloop Face Masks.	K012602	01/22/2002

Device Description

The IMC Surgical Face Mask devices are surgical apparel intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. The surgical masks feature either tie-on or ear loop attachment mechanisms

This device is a flat pleated 3 ply mask. The inner and outer layer of the mask is made of polypropylene, sandwiching a middle layer made of melt-blown polypropylene filter media. The outer layer of the mask is offered in a yellow color.

Statement of Intended Use

Indications For Use: This device is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

Name/Description	Sterility
• IMC Surgical face mask Yellow with Ear loop	Sterile
• IMC Surgical face mask Yellow with Tie-on	Sterile
• IMC Surgical face mask Yellow with Ear loop	Non-Sterile
• IMC Surgical face mask Yellow with Tie-on	Non-Sterile

New Devices as Compared to Marketed Device(s)

The IMC Surgical Mask and the predicate devices (Medline Prohibit Series Surgical Mask With Fluid Shield and the Crosstex series: Isolite Earloop Face Masks and Isofluid Earloop Face Masks) are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

Feature/ Characteristic	IMC Surgical Face Mask K100846	Medline K991559 (Predicate)	Crosstex K012602 (Predicate)
Material			
Layer 1 - Outer	These materials were tested in accordance with ISO 10993-5, 10993-10, and 10993-11 test methods and were found to be acceptable for the intended use	Same	Same
Layer 2 – Middle	These materials were tested in accordance with ISO 10993-5, 10993-10, and 10993-11 test methods and were found to be acceptable for the intended use	Same	Same
Layer 3 - Inner	These materials were tested in accordance with ISO 10993-5, 10993-10, and 10993-11 test methods and were found to be acceptable for the intended use	Same	Same
Ear loop	These materials were tested in accordance with ISO 10993-5, 10993-10, and 10993-11 test methods and were found to be acceptable for the intended use	Same	Same

Feature/ Characteristic	IMC Surgical Face Mask K100846	Medline K991559 (Predicate)	Crosstex K012602 (Predicate)
Tie-on	These materials were tested in accordance with ISO 10993-5, 10993-10, and 10993-11 test methods and were found to be acceptable for the intended use	Same	Same
Nose Piece	These materials were tested in accordance with ISO 10993-5, 10993-10, and 10993-11 test methods and were found to be acceptable for the intended use	Same	Same
colors			
Yellow	These materials were tested in accordance with ISO 10993-5, 10993-10, and 10993-11 test methods and were found to be acceptable for the intended use	Same	Same
Specification and Dimensions:			
Dimension			
• Length	7 inches	Similar	Same
• Width	3.5 inches	Similar	Same
Mask Style	Ear loop	Same	Same
	Tie-on	Same	Same
Design Features	Flat pleated	Flat pleated, cone-style	Flat pleated, molded

Performance Data:

Performance Characteristics	Test Method	Acceptance Criteria	IMC Surgical Face Mask K100846	Medline K991559 (Predicate)	Crosstex K012602 (Predicate)
Fluid Resistance Performance (mmHg)	ASTM F1862-07 (2007)	Low=80 Moderate = 120 High = 160	Meets Standard Criteria	Same	Same
Particulate Filtration Efficiency Performance (%)	ASTM F2299-03 (2003)	≥98%	Meets Standard Criteria	Same	Same
Bacterial Filtration Efficiency Performance (%)	ASTM F2101-07 (2007)	Low: ≥95 Moderate: ≥98% High: ≥98%	Meets Standard Criteria	Same	Same
Different Pressure (Delta-P) *(mmH_2O/cm^2)*	MIL-M36945C 4.4.1.1.1 (1975)	≤4 mmH2O/cm2	Meets Standard Criteria	Same	Same
Flammability	16 CFR Part 1610 (1998)	Class 1	Class 1	Same	Same

Conclusions:

The indications for use, technology, specification, safety of the IMC Surgical Face Masks and the two predicate devices K991559 and K012602 are essentially the same. The differences between the face masks are minor and do not raise new issues of safety or effectiveness. Hence, the IMC Surgical Face Masks are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

International MedSurg Connection
C/O Mr. Peter Kim
935 North Plum Grove Road, Suite F
Schaumburg, Illinois 60173

AUG 16 2010

Re: K100846
Trade/Device Name: IMC Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: July 28, 2010
Received: August 2, 2010

Dear Mr. Kim:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100846

Indications for Use

510(k) Number : K100846

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Prescription Use ___ ____ AND/OR Over-The-Counter Use ____X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elaine S. Maykall for Elizabeth F. Claverie
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100846

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