510(k) SUMMARY

JUL 14 2010

510(k) Number: K093179

Submitted by Owner: Jong T. Huang, MD, FACP
President
H & H Research Company
1245 Wilshire Blvd., No. 501
Los Angeles, CA 90017
Tel: 213-977-1257 Fax: 213-977-9071
Email: drjhuang@gmail.com

Date of Preparation: June 9, 2010

Name of Device: The New Medical Mask

Classification Name and Product Code:
Medical Mask; Surgical Apparel (21CFR878.4040)
Product Code: FXX

SUMMARY STATEMENT:

Predicate Products: TIDI™ Facemask, Tidi Products, LLC: K092580
Spunguard Mask, Kimberly-Clark: K823078
3M Particulate Respirator and Surgical Mask Model 1870: K063023

Comparison of Intended Use:

This product is indicated for infection control practices in the health care industry.

When worn properly, The New Medical Mask is intended to protect both patient and wearer from the transfer of microorganisms, body fluids and particulate material.

Predicates:
TIDI Facemask - The TIDI Facemasks by Tidi Products, LLC, are surgical masks intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating personnel from transfer of microorganisms, body fluids and particulate material.

Spunguard - The Spunguard mask is intended to protect both the patient and the wearer from transfer of microorganisms, body fluids, and particulate material.

3M Particulate Respirator and Surgical Mask Model 1870 - As a respirator, it is intended to help reduce wearer exposure to certain airborne particles including those generated by

electrocautery, laser surgery, and other powered medical instruments. As a surgical mask, it is designed to be fluid resistant to splash and spatter of blood and other infectious materials.

Comparison of Design Characteristics: Predicate = TIDI Facemask

Feature	The New Medical Mask	Predicate (K092580)
Style	flat	flat pleated
Attachment	non-latex elastic ear bands	non-latex elastic ear loops
Nose	adhesive tape	malleable aluminum
Filter Material	polypropylene	polypropylene
Covering	polypropylene	polypropylene
Length	7.1 inches (18 cm)	7.0 inches
Width	3.9 inches (10 cm)	3.5 inches
Sterile	No	No
Single Use	Yes	Yes

Comparison of Performance Characteristics: Predicate = TIDI Facemask

Both products meet the requirements of ASTM F 2100 - 07, Standard Specification for Performance of Materials Used in Medical Face Mask, as demonstrated below:

Performance Characteristics	The New Medical Mask	Predicate K092580
Bacterial Filtration Efficiency Performance (%) (ASTM F 2101)	>99.9% High Barrier	>99.9% High Barrier
Differential Pressure (Delta-P) (mm H_2O/cm^2) (MIL-M-36954C)	2.7 mm H_2O/cm^2 Low Barrier	3.4 mm H_2O/cm^2 Low Barrier
Sub-micron Particulate Filtration Efficiency at 0.1 micron Performance (%) (ASTM F 2299)	99.9% High Barrier	99.6% High Barrier
Resistance to penetration by synthetic blood, Minimum pressure in mmHg for pass results. (ASTM F 1862)	Pass at 160 mmHg	Pass at 80 mmHg
Flammability Class (16 CFR Part 1610)	Class 1	Class 1

Conclusion:

The New Medical Mask has the same intended use as the predicate devices. It has the same design and performance characteristics as the TIDI Facemask and presumably of any other mask that meets the Standard Specification, ASTM F 2100 and which followed the FDA Guidance - Surgical Mask Premarket Notification [510(k)] Submission; Guidance for Industry and FDA (3/5/05, 9/14/07) during development.

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

Mr. Jong Huang
President
H & H Research Company
1245 Wilshire Boulevard #501
Los Angeles, California 90017

JUL 14 2010

Re: K093179
Trade/Device Name: The New Medical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: June 9, 2010
Received: June 17, 2010

Dear Mr. Huang:

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

Indications for Use

510(k) Number (if known): K093179

Device Name: The New Medical Mask

Indications For Use:

This product is indicated for infection control practices in the health care industry.

When worn properly, The New Medical Mask is intended to protect both patient and wearer from the transfer of microorganisms, body fluids and particulate material.

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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