K040485

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

OCT 18 2004

Summary Date:	February 11,2004
Company/Institution: Name and address	Bio-Medical Devices, Inc. 17171 Daimler Ave Irvine, Ca 92614 949-752-9642 PH 949-752-9658 Fax
Contact Name:	Nick Herbert 949-752-9642 Ph ext. 113 President 949-752-9658 Fax
Classification Name:	Surgical Gown
Device Product Code:	79 FYA
Regulation Number:	878.4040
Device Trade Name:	MAXair® Surgical Helmet system
Establishment Registration Number:	2083467
Classification:	Class II
Predicate Device:	The predicate device is the Stryker T4 personal protection system (Ref:K993148)
Substantial Equivalence:	The MAXair® Surgical Helmet system is substantially equivalent to the Stryker T4 Personal Protection System. • The intended use is the same • Materials are identical • Manufacturing process is identical • Packaging is identical • Sterilization process is identical • The design is similar The filtration efficiency of the MAXair surgical system is Comparable to the Stryker Steri-shield system and is additionally NIOSH approved.

Intended Use and device description:

The MAXair Surgical Helmet system consists of disposable surgical apparel and re-usable headgear, battery pack and accessory battery charger. The MAXair Surgical Helmet system 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.

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The disposable, sterile surgical apparel of the MAXair system includes an electrostatically charged meltblown fabric hood/filter and a barrier toga. The barrier material is fluid resistant to protect the wearer from fluid borne pathogens. Testing has shown that the barrier materials pass ASTM standard test F1670 for resistance to synthetic blood and F1671 for resistance to penetration by blood borne pathogens using viral penetration (see section J for test results). The meltblown fabric hood/filter has passed NIOSH testing (TC-21C-0775) for PAPR's and is rated HE (High Efficiency) (see section J for test results).

The non-sterile, re-usable component of the Surgical Helmet system is comprised of a self contained Helmet/blower and a battery pack. The helmet has an incorporated headgear and provides air delivery. The air delivery helmet pulls air from outside the hood/filter, through the filter media, and directs it inside to the user. The system is powered by a lithium ion battery pack. The lithium ion battery pack is re-charged by an accessory battery charger.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2004

Mr. Nick Herbert
President
Bio-Medical Devices, Incorporated
17171 Daimler Avenue
Irvine, California 92614

Re: K040485
Trade/Device Name: MAXair® Surgical Helmet System
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: October 8, 2004
Received: October 8, 2004

Dear Mr. Herbert:

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.

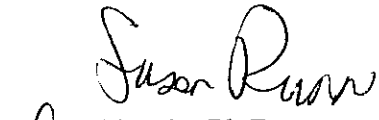
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K040485

Device Name: MAXair® Surgical Helmet system

Indications For Use:

The MAXair Surgical Helmet system 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. The MAXair Surgical Helmet system consists of disposable surgical apparel and re-usable headgear, battery pack and accessory battery charger.

Prescription Use__X___ AND/OR Over-The-Counter Use_____
(Per 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)

Kevin Mulvey

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

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