K971130 JUN 27 1997

XII. 510(k) SUMMARY FOR K-971130, DEFEND® SURGICAL MASK

A. Submitter: Andrew Parker, Carl Parker Assoc. Inc., 275 Oser Ave., Hauppauge, NY 11788

I. Classification Names and numbers: Surgical Mask, 79FXX
II. Common/Usual Name: Surgical Mask
III. Proprietary Names: DEFEND™ Surgical Mask
IV. Establishment Registration Number: 2433028
V. Classification: Surgical masks were classified by the General and Plastic Surgery Panel in Class II under code 79FXX and are listed in CFR 878.4040 as "Surgical Apparel." Most examples are Class I except for surgical gowns and masks which are Class II.
VI. Performance Standard: None established under section 514.
VII. Description of the Device: These disposable surgical masks are formed of three layers and are flat-fold disposable face masks comprised of two segments which form a comfortable mask covering the nose and mouth areas of the face. The outer mask surface is of non-woven polypropylene. The middle layer, between the non-woven outer and inner layers, is made of "meltblown" air filtration media. This material is designed as a highly efficient bacterial filter with very low pressure drop, to facilitate breathing and minimize spectacle fogging. The facial layer is of non-woven polypropylene. The mask is designed to be resistant to penetration even when body fluids strike it with impact, while allowing cool, comfortable breathing.
VIII. Labels of the product and competitive devices are provided.
IX. Substantial Equivalence Statement. The "510(k) "Substantial Equivalence" Decision process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, to act as physical barrier including fluid-resistant properties, provide only very low impediment to breathing, avoid fogging of surgeons glasses, effective filtration of particles, droplets, not hinder speech. These are the same as those of the predicate devices. These products also have the same intended uses as similar products currently cleared for marketing by the 510(k) process.
2. The technological characteristics for this product are the same as those for the predicate devices and those currently on the market.
3. Descriptive information provided shows that the materials from which the Fluid Resistant Pleated Mask is made are substantially equivalent to (nearly identical with) those of similar products, used for identical purposes, currently on the market.
4. Test data supplied to show the equivalence of this device to Technol and others cited below included:
    a. Penetration by Water Impact Test;
    b. Sensitization test;
    c. Primary Dermal Irritation test;
    d. Particulate Shedding analysis,
    e. Flammability; and
    f. Cytotoxicity.
    g. Filtration Efficiency, Breathability

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VI. Performance Standard:

None established under section 514.

VII. Description of the Device:

Drawings of the Defend Surgical Mask appear in Attachment I. These are intended to be exemplary rather than exhaustive. The mask is formed of three layers and is a flat-fold disposable face mask comprised of pleated segments which open to form a comfortable mask covering the nose and mouth areas of the face. The sides are secured by binding tapes to which is attached the elastic band to secure the mask to the face. The top and bottom of the mask are fused to prevent fabric delamination.

The outer mask surface is of Spunbond non-woven polypropylene (20 g/m^2). The middle layer, between the non-woven outer and inner layers, is made of meltblown air filtration media. The characteristics of this media are listed in Attachment VI. This material is designed as a highly efficient bacterial filter with very low pressure drop, to facilitate breathing and minimize spectacle fogging. The facial layer is of Thermobond non-woven polypropylene (15 g/m^2). The characteristics of the two outer layers are also listed in Attachment VI. The mask is designed to be resistant to penetration even when body fluids strike it with impact, while allowing cool, comfortable breathing.

The mask has a light aluminum strip which bends readily to fit closely over the nose, diminishing fogging of spectacles. It also has a light foam strip fused to this edge to provide more effective coverage and user comfort. Two woven elastic ear loops complete the mask.

The products will be sold non-sterile, prepackaged, and are disposable, for single use only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Carl Parker Associates, Incorporated
C/O Mr. Neal Dunning
Neal Dunning Associates, Incorporated
8309 Byrant Drive
Bethesda, Maryland 20817

Re: K971130
Trade Name: Defend Surgical Mask
Regulatory Class: II
Product Code: FXX
Dated: May 20, 1997
Received: June 10, 1997

JUN 27 1997

Dear Mr. Dunning:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VIII.1 Indications for Use: [Separate Page]

510(k) Number: Not Applicable

Device Name: DEFEND™ Surgical Mask

1. Intended to be worn by operating room personnel to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids and particulate material.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K971130

Prescription Use_____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)