JAN 27 1997

XII. SAFE MEDICAL DEVICES ACT OF 1990 SUMMARY OF SAFETY AND EFFECTIVENESS. Jan. 16, 1997. [Separate Pages] K962657

A. Submitter Andrew Parker, Car 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 Conpleat™ 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 arcuate 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 "Web Dynamics" 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 Conpleat Surgical 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. Synthetic Blood Penetration Resistance Test, Protocol 9617002-01 selected as more definitive than Penetration by Water Impact Test,

   b. Bacterial Filtration Efficiency and Delta P tests;

   c. Primary Dermal Irritation test,

   d. Particulate Shedding analysis, flammability, and

   e. Cytotoxicity

Repl. p.8

4 The FDA "Decision-Making Process" chart was used.
The Conpleat Surgical Mask is substantially equivalent to the originally classified device, described under CFR 878 4040, to preamendment devices and to devices currently on the market, cleared by the the 510(k) process The Conpleat Surgical Mask is substantially equivalent to (for example) the following devices: Softwear, Fluid Resistant Masks, Busse Hosp Disposables, K-830890, Fluid Shield Procedure Mask, Technol Inc., K-9321375, Fluid Resistant Mask, Mid America Medical, Inc., K-934974.

End of Summary

Repl. p. 8a