APR - 2 2001

K001997
510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

White Knight Engineered Products
9209-A Forsyth Park Dr.
Charlotte, NC 28273

Phone: 704-504-1150
Fax: 704-588-3817

Contact Person: Ted Dubose

Date of Summary: March 23, 2001

Trade Name: White Knight Shield Mask

Classification Name: Mask, Surgical

Predicate Device:

White Knight Precept Rayon Mask	Pre-Amendment
White Knight Comfort-Cool Mask	Pre-Amendment
White Knight Comfort Elite Mask	Pre-Amendment

Intended Use: The mask / shield is intended to be used by operating room personnel during surgical procedures to protect both the surgical patients and operating room personnel from the transfer of microorganisms, body fluids and particulate materials.

Device Description/ Comparison: These masks are made with a rayon inner and polypropylene outer facing and media. The masks are identical to the predicate device, which were also made by White Knight. The masks may have a shield to provide additional protection. These masks have been tested under a number on non-clinical test conditions.

K001997

Product Testing: A number of tests have been completed for this product to demonstrate it being substantially equivalent to the predicate. This testing included BFE, particulate, pressure differential (Delta P), EFF and Flammability. This information has been included in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2001

White Knight Healthcare, Incorporated
C/O Mr. Art Ward
Regulatory Consultant
Regulatory & Marketing Services, Incorporated
3234 Ella Lane
New Port Richey, Florida 34655

Re: K001997
Trade Name: White Knight Blue, Green Face Mask, (4 Models)
Regulatory Class: II
Product Code: FXX
Dated: March 23, 2001
Received: March 26, 2001

Dear Mr. Ward:

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 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). 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 requirements, 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) 594-4692. 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" (21CFR 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/dsma/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

510(k) Number (if known): K001997

Device Name: White Knight Shield Mask, Blue/Green (4 models)

Indications For Use:

The mask / shield is intended to be used by operating room personnel during surgical procedures to protect both the surgical patients and operating room personnel from the transfer of microorganisms, body fluids and particulate materials.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001997