

K972832

**SUMMARY OF SAFETY AND EFFECTIVENESS**

OCT 21 1997

**NAME OF FIRM:** DePuy Orthopaedics, Inc.  
700 Orthopaedic Drive  
Warsaw, In 46581-0988

**510(k) CONTACT:** Cheryl K. Hastings  
Manager, Clinical Affairs

**TRADE NAME:** ProVision Surgical Helmet System

**CLASSIFICATION:** 878.4040 Surgical apparel

**DEVICE PRODUCT CODE:** 79 FYA

**SUBSTANTIALLY EQUIVALENT DEVICES:**  DePuy Sterile View Surgical Exhaust System

Sterile View Disposable Barrier Hood/Gowns

DePuy Disposable Filter/Hood

Stackhouse FreedomAire Surgical Helmet System

Stryker Steri Shield Turbo III

**INTENDED USE AND DEVICE DESCRIPTION:**

The ProVision Surgical Helmet System consists of disposable surgical apparel and re-usable headgear, battery holder and battery pack. The ProVision Surgical Helmet System is intended to be worn by healthcare workers in the operating room during surgical procedures to protect both the healthcare worker and the surgical patient from the transfer of microorganisms, body fluids and particulate material.

The disposable, sterile surgical apparel of the ProVision system include a barrier hood/gown with Hytrel® elastomer, a barrier hood/gown toga with Hytrel, a barrier hood with Hytrel and a paper hood. A molded, polycarbonate face shield is sealed to the hood material. The Hytrel coated material is fluid resistant but vapor transmissive. The gown, toga and hood with Hytrel therefore protect the wearer from fluid borne pathogens, while maintaining "breathability". The barrier hood/gown and barrier hood/gown toga each come in three sizes. Testing has shown that the Hytrel coated material of the barrier hood/gown and barrier hood/gown toga passes ASTM standard test ES-21 for resistance to synthetic blood and ES-22 for resistance to penetration by blood borne pathogens using viral penetration as a test system.

The non-sterile, re-usable component of the ProVision system is a two piece unit comprised of a helmet and a battery pack. The helmet is a headgear supporting an air delivery system. The air delivery system pulls air from outside the hood or hood/gown, through a filter media, and directs

000004

it to the wearer's face/neck area. The air delivery system is powered by a nickel metal hydride battery pack.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The ProVision Surgical Helmet System is similar in design and identical in use to the DePuy Sterile View Surgical Exhaust System combined with the Sterile View Barrier Hood/Gowns. The system has been modified to make it more comfortable and compact, lighter, cooler and quieter while maintaining adequate filtration. The filtration efficiency of the ProVision Surgical Helmet System is comparable to that of the DePuy Disposable Filter Hood.

The ProVision Surgical Helmet System is also similar in design and intended use to the Stackhouse FreedomAire Surgical Helmet System and the Stryker Steri Shield Turbo III.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

OCT 21 1997

Ms. Cheryl K. Hastings  
Manager, Clinical Affairs  
DePuy, Incorporated  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988

Re: K972832  
Trade Name: Provision Surgical Helmet System  
Regulatory Class: II  
Product Code: FYA  
Dated: July 29, 1997  
Received: July 30, 1997

Dear Ms. Hastings:

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.

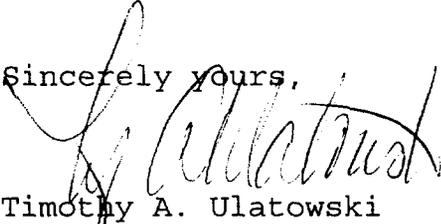
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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

510(k) Number (if known) K972832

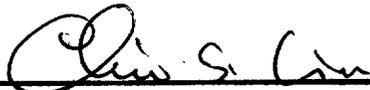
Device Name ProVision Surgical Helmet System

Indications for Use:

The ProVision Surgical Helmet System consists of disposable surgical apparel and re-usable headgear, battery holder and battery pack. The ProVision Surgical Helmet System is intended to be worn by healthcare workers in the operating room during surgical procedures to protect both the healthcare worker and the surgical patient from the transfer of microorganisms, body fluids and particulate material.

---

Concurrence of CDRH, Office of Device Evaluation



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

510(k) Number K972832

Prescription Use \_\_\_\_\_

OR  
(Per 21 CFR 801.109)

Over-The Counter Use X

000001