K971742

SAFETY AND EFFECTIVENESS SUMMARY

JUL 24 1997

NAME OF FIRM:

DePuy, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
FDA Registration No.: 1818910

FIRM CONTACT:

Arlene Saull, RAC
Manager, Medical Device Submissions
DePuy Orthopaedics, Inc. (a subsidiary of DePuy, Inc.)
700 Orthopaedic Drive
Warsaw, IN 46581-0988

TRADE NAME: DePuy OrthoTech Heavy Duty Vest Restraint

COMMON NAME: Protective Restraints

CLASSIFICATION: Class I per 21 CFR, 880.6760 Protective Restraint

DEVICE PRODUCT CODE: 80 FMQ Restraint, Protective

SUBSTANTIALLY EQUIVALENT DEVICES:

Zimmer Heavy Duty Vest Restraint, and
DePuy Vest Restraint with Sleeves (K963393)

DEVICE DESCRIPTION AND INTENDED USE:

The body of the vest restraint is constructed from three main pattern pieces, two front panels and a back panel which are cut from polyester mesh fabric. The vest comes equipped with four pairs of long straps which are used for securing the patient to the chair, wheelchair or bed. The subject vest restraint is supplied in five sizes from X-small to X-large to fit chests from 28" to 56". It may be hand washed in warm water and air dried.

The DePuy OrthoTech Heavy Duty Vest Restraint is intended to limit body movement and provide support for patients in chairs, wheelchairs and beds who (a) may be susceptible to life-threatening falls, (b) may be suicidal, or (c) are aggressive..

BASIS OF SUBSTANTIAL EQUIVALENCE:

Based on their similarities in design, construction, materials, and intended uses, DePuy, Inc. considers the subject DePuy OrthoTech Heavy Duty Vest Restraint as substantially equivalent to the DePuy Mesh Vest Restraint with Sleeves which was cleared by FDA in 510(k) K963393 and the Zimmer Inc. Heavy Duty Vest Restraint.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Arlene C. Saull
Manager, Medical Device Submission
DePuy, Incorporated
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

JUL 24 1997

Re: K971742
Trade Name: DePuy Orthotech Heavy Duty Vest Restraint
Regulatory Class: I
Product Code: FMQ
Dated: May 9, 1997
Received: May 12, 1997

Dear Ms. Saull:

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

INDICATIONS

510(k) Number (if known) K971742

Device Name DePuy OrthoTech Heavy Duty Vest Restraint

Indications for Use:

The DePuy OrthoTech Heavy Duty Vest Restraint is intended to limit body movement and provide support for patients in chairs, wheelchairs and beds who (a) may be susceptible to life-threatening falls, (b) may be suicidal, or (c) are aggressive.

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off) Patricia Cucenta
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971742

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)