FAIRMONT MEDICAL

OCT - 9 1997

510(k) SUMMARY

510(k): K 972130

Fairmont Medical Products, Pty., Ltd.
Factory 4, 21 Malvern Street
Bayswater, Victoria 3153
Australia

Telephone: 613 9720-8840
Facsimile: 613 9720-8860

Contact: JoAnne McBain

Date: 9 September 1997

Trade Name: Disposable Universal X-Ray Cover
Code Number: DXC 8015
Trade Name: Disposable Mini X-Ray Cover
Code Number: DXC 8025

510(k) Number: K 972130

The Disposable X-Ray Cover is a sterile cover or drape for operative X-ray machines utilised during surgical procedures which require a sterile environment. It allows a surgeon to adjust and manoeuvre at will, without compromising the sterile field.

As with most major surgical equipment, X-ray machines cannot be sterilised. It would damage them, rendering them useless. The Disposable X-Ray Cover provides a sterile barrier between the patient and the X-ray machine. Contaminants from operative equipment (the X-ray machine) cannot penetrate through to infect the patient. Patient contaminants (such as blood and bodily fluids) cannot penetrate through to damage the machine. The DXC is disposable and single patient use only, so there is no cross contamination between patients. It is sterilised via gamma radiation.

Clinical testing for viral penetration has demonstrated that the Disposable X-Ray Cover allows no penetration of virus and provides effective protection against viral penetration.

This product is marketed towards surgeons and hospitals concerned with the convenience and protection of covering an operative X-ray machine, so that it will not contaminate the sterile field.

FAIRMONT MEDICAL

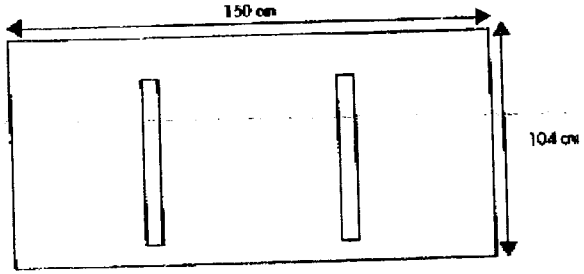
:1 Malvern Street, Bayswater, Victoria. 3153
one: (03) 9720 8840 Fax: (03) 9720 8860

Universal X-Ray Cover

CAT NO. 8015

STERILE

DISPOSABLE



BATCH NO:

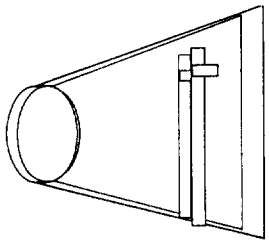
STERILE IF PACK UNOPENED OR UNDAMAGED · SINGLE PATIENT USE

FAIRMONT
MEDICAL
4/21 Malvern Street, Bayswater, Victoria. 3153
Phone: (03) 9720 8840 Fax: (03) 9720 8860

Mini X-Ray Cover

STERILE

DISPOSABLE



CAT NO. 8025

BATCH No.

STERILE IF PACK UNOPENED OR UNDAMAGED - SINGLE PATIENT USE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Ms. JoAnne McBain
Quality Assurance
Fairmont Medical
4/21 Malvern Street
Bayswater, Victoria
Australia

OCT - 9 1997

Re: K972130
Trade Name: Disposable Universal X-Ray Covers
Regulatory Class: II
Product Code: IZJ
Dated: September 18, 1997
Received: September 24, 1997

Dear Ms. McBain:

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

510(k) Number (if known): K972130

Device Name: Disposable X-Ray Cover

Indications For Use:

The Disposable X-Ray Cover is a sterile cover or drape for operative X-ray machine utilised during surgical procedures which require a sterile environment. It allows a surgeon to adjust and manoeuvre at will, without compromising the sterile field.

The DXC provides a sterile barrier between the patient and the X-ray machine. Contaminants from the operative equipment (the X-ray machine) cannot penetrate through to infect the patient. Patient contaminants (such as blood and bodily fluids) cannot penetrate through to damage the machine. The DXC is disposable and single patient use only, so there is no cross contamination between patients. It is sterilised via gamma radiation.

This product is marketed towards surgeons and hospitals concerned with the convenience and protection of covering an operative X-ray machine, so that it will not contaminate the sterile field.

(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 K972130

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

(Optional Format 1-2-96)