K982832

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16. Summary of Safety and Effectiveness

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

This product contains natural rubber latex. The gloves are a product of Malaysia.
The manufacturer of these latex-lead gloves complies with all the current specifications listed under The American ociety for testing and Materials (ASTM) Specification D 3578 – 91 and FDA Water Leak Test.

The quality assurance testing for the finished product includes testing for physical properties such as tensile strength and elongation; dimensions such as length, width and thickness; visual tests such as such as colour and material uniformity. In addition, sampling and testing for leaks conforms to the FDA Water Leak Test for patient examination gloves.

Intended use of the gloves:
The X-Ray protection gloves PROGUARD are sterile examination gloves, radio-opaque, to be worn by hospital personnel, specifically surgeons, to protect their hands from radiation during operation of x-ray equipment.These gloves are destined to specific examination purposes. They are not intended to be used instead of a Radiographic Protective Gloves, normally used in radiography for those studies which need the physician's hands or forearms to be inserted intop the primary x-ray beam, but not the sterility or the degree of manual dexterity allowed by the PROGUARD.
Moreover these gloves are not to be used in or next to the primary x-ray beam or conducted primary x-ray beam. The main purpose of these gloves is to reduce the amount of dispersed radiation exposure to the hands from the primary x-ray beam during examinations or procedures under fluoroscopy performance.

The following caution statement is included in the product labelling:

CAUTION:
The PROGUARD glove is a specialty glove intended for specific examination purposes. It is not intended for uses in or adjacent to the primary x-ray beam. The intent of this glove is to reduce the amount of scattered radiation exposure to the hands from the primary x-ray beam during fluoroscopic examination; e.g. percutaneous renal calculus removal, percutaneous transhepatic cholangiography procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 1998

Stefano Costigliolo
Chairman
Emerson & Co. S.R.L.
10, Piazza Della Vittoria
16121 Genova Italia

Re: K982832
Proguard RR-1, RR-2 X-Ray Protection Gloves
Dated: November 19, 1998
Received: November 23, 1998
Regulatory class: I
21 CFR 880.6250/Procode: 80 LZC

Dear Mr. Costigliolo:

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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indication for use Statement

Applicant : Emerson & Co. S.r.l.
510(k) Number : Not available
Device Name : X-Ray protection glove
Trade Name : PROGUARD

Indication for use :
The X-Ray protection gloves PROGUARD are sterile examination gloves, radio-opaque, to be worn by hospital personnel, specifically surgeons, to protect their hands from radiation during operation of x-ray equipment.These gloves are destined to specific examination purposes. They are not intended to be used instead of a Radiographic Protective Gloves, normally used in radiography for those studies which need the physician's hands or forearms to be inserted intop the primary x-ray beam, but not the sterility or the degree of manual dexterity allowed by the PROGUARD.
Moreover these gloves are not to be used in or next to the primary x-ray beam or conducted primary x-ray beam. The main purpose of these gloves is to reduce the amount of dispersed radiation exposure to the hands from the primary x-ray beam during examinations or procedures under fluoroscopy performance.

Concurrence of CDHR Office of Device Evaluation (ODE)

Prescription Use ___1___ OR Over the counter _____
Per 21 CFR 801.109