

MAY 19 1998

K981169

RONDEX PRODUCTS, INC.
P.O. Box 1829
Rockford, Illinois
May 4, 1994
phone: 815-226-0452
contact: Gene R. Baldwin

Device Name: CPR ISO-SHIELD
Common Name: CPR Shield
Predicate Devices:
a. Microshield
b. Res-Cue Key

510K SUMMARY OF SAFETY AND EFFECTIVENESS

The CPR ISO-SHIELD is a device designed as an adjunct for mouth-to-mouth ventilation on a non-breathing adult or child while helping to isolate the operator's mouth from the victim's body fluids.

The CPR ISO-SHIELD has a shield barrier, a plastic bite block/air tube with valve which is placed between the victim's teeth. The operator blows into the tube and uses acceptable CPR procedures. The victim's exhalation is possible by their breath escaping around the valve and between the shield and their face.

Design characteristics: The large surface area of the barrier, 49 square inches reduces the risk of vomitus escaping around the sides of the shield and coming in contact with the operator's face side of the shield. Two plastic grips are added to the ISO-SHIELD, attached to the valve housing below the barrier on the victim's side. This allows the operator to handle the device under the protective barrier to minimize the transfer of contamination to the top surface. These grips also have memory which should help lift the shield from the victim's face after the operator releases his mouth.

The technological characteristics of the device differ somewhat from Microshield. ISO-SHIELD has a polyethylene plastic barrier. Microshield uses vinyl (PVC ?). Res-Cue Key appears to use polyethylene material.

ISO-SHIELD uses a silicone rubber flapper design for the valve. This is similar to Res-Cue Key. This results in less air flow back pressure by the operator blowing into the valve as compared to Microshield.

The ISO-SHIELD has two plastic grips attached to the valve housing. Microshield and Res-Cue Key do not have this feature. The grips allows the operator to position and remove the shield without touching the top surface. Touching the top surface increases the risk of contamination being transferred to the blowing surface where the operator puts his lips. The grips also help release the shield from the victim's face after the operator releases his mouth.

SAFETY & EFFECTIVENESS TO OTHER MARKETED PRODUCTS:

The victim can breathe spontaneously, if they have the ability, without operator assistance when the device is in place and the shield is released from the victim's face. Same as Microshield.

The CPR ISO-SHIELD has a means to help lift the shield barrier away from victim's face to facilitate exhalation especially if the operator pinches the nose closed on top of the shield. Microshield and Res-Cue Key do not offer this.

Device can be handled beneath the protective shield barrier, the victim's side, to increase safety to the operator against contamination being transferred to the operator's face side of the shield. Microshield and Res-Cue Key do not offer this.

Effective resuscitation was achieved using the technique similar to mouth-to-mouth resuscitation on an adult Laerdal Anne and Armstrong child manikin Timmy. Sealing and ventilation effectiveness were equivalent to Microshield.

ISO SHIELD has a 4 mil polyethylene shield barrier. Ambu's Res-Cue Key uses a 1 mil (polyethylene?) material for the shield barrier. This thickness, 1 mil, is very thin and there is high risk of it tearing on the victim's or operator's teeth or beard stubble. Microshield has a 12 mil vinyl material.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Gene R. Baldwin
Rondex Products, Inc.
P.O. Box No. 1829
Rockford, IL 61110

Re: K981169
CPR Shield
Regulatory Class: II (two)
Product Code: 73 LYM
Dated: March 25, 1998
Received: March 30, 1998

Dear Mr. Baldwin:

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.

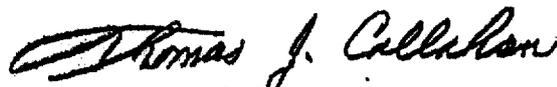
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Gene R. Baldwin

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) 594-4648. 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K981169/A

510(k) NUMBER (IF KNOWN): K981169

DEVICE NAME: Rondex CPR Iso-Shield

INDICATIONS FOR USE:

To provide a means for a person to administer artificial ventilation using the mouth-to-mouth technique while reducing the risk of the operator's mouth coming in contact with body fluids from the non-breathing victim.

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FDA/CDRH/ODE/DMC

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)

M. Pugh
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K981169

SK-15