K090284

JUN - 5 2009

510(k) Summary

Submitter's Information:	CR Enterprises, LLC 4701 Augusta Dr Frisco TX 75034 Contact: Craig A. Troop, M.D. Phone: 972-625-5177 December 15, 2008
Device/Classification Name	Device Name: RES-Q Infant Wedge & Sling Classification/Common Name: Holder, Infant Positioner Code FRP, CFR 880.5680
Class	Class 1
Predicate Devices	Pedicraft Reflux Wedge – 510(k) #K905629 Tucker Sling – 510(k) #K932636
Intended Use	The RES-Q Infant Wedge & Sling is designed to allow babies 0-12 months with gastro-esophageal reflux to rest comfortably in a semi-upright position; it is used for sleeping and playtime in supine, prone, and side-lying positions.
Performance Summary	FDA has not established special controls or performance standards for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Craig A. Troop, M.D.
Manager
C.R. Enterprises, LLC
4701 Augusta Drive
Frisco, Texas 75034

JUN - 5 2009

Re: K090284
Trade/Device Name: RES-Q Infant Wedge and Sling
Regulation Number: 21 CFR 880.5680
Regulation Name: Holder, Infant Positioner
Regulatory Class: I
Product Code: FRP
Dated: May 20, 2009
Received: June 2, 2009

Dear Dr. Troop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., MA
Acting Division Director
Division of Anesthesiology, General
Hospital, Infection Control and Dental
Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090284

Indications For Use

510(k) Number (if known): K090284

Device Name: RES-Q Infant Wedge & Sling

Indications for Use:

The RES-Q Infant Wedge & Sling is designed to allow babies 0-12 months with gastro-esophageal reflux to rest comfortably in a semi-upright position; it is used for sleeping and playtime in supine, prone, and side-lying positions.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sid Mussi for LCDR. Colburn

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

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