AUG 3 0 2005

K051979

SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitters Identification:

   O.R. Solutions, Inc.
   3901 Centerview Drive, Suite L
   Chantilly, Virginia 20151

   Date of Summary June 17, 2005

2. Device Name: ORS 6000 Endoscope Holder

3. Classification Name: Warmer, Irrigation, Solution, Accessory

4. Predicate Devices:
   Karl Storz KSEA Endoscope Holder K990334

5. Description

   The ORS 6000 Endoscope Holder (figures 1) is designed to prevent fogging or wetting of the scope eyepiece by providing a hold for the scope, which keeps it above the water line of the warm solutions.

   The ORS 6000 Endoscope Holder is manufactured from GE VALOX thermoplastic polyester resins. The ORS Endoscope Holder is a single use disposable device. The ORS 6000 Endoscope Holder is used with ORS-2000 Solution Warmer K921633 and ORS-2000LD Solution Warmer K021289.

6. Indications for Use

   The ORS 6000 Endoscope Holder is a single use disposable device as an accessory for ORS Solution Warmers. The ORS 6000 Endoscope Holder is designed to hold optical end of various endoscopes above the warm solution to prevent fogging or wetting of the scope eyepiece.

7. Biocompatibility

   Cytotoxicity Test
   Systemic Injection Test
   Intracutaneous Injection Tests
   Dermal Sensitization

8. Substantial Equivalence

Parameters	ORS 6000	Storz
510(k) Number		K990334
Intended Use:	The ORS 6000 Endoscope Holder is a single use disposable device as an accessory for ORS Solution Warmers. The ORS 6000 Endoscope Holder is designed to hold optical end of various endoscopes above the warm solution to prevent fogging or wetting of the scope eyepiece.	The KSEA Endoscope Holder is intended for use by qualified surgeons for holding rigid and flexible endoscopes during diagnostic and therapeutic neurologic procedures.
Material Choice	Thermoplastic polyester resins	Stainless Steel and Anodized Aluminum
Meets Biocompatibility Standards	Yes	Yes
Reusable/Disposable	Disposable	Reusable

The ORS 6000 Endoscope Holder does not raise any new issue concerning safety and effectiveness. Both the Storz and ORS 6000 product meet biocompatibility standards and both are used for similar purpose(s), which is holding an endoscope during a procedure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2005

O.R. Solutions, Inc.
c/o Mr. E. J. Smith
Smith Associates
PO Box 4341
Crofton, Maryland 21114

Re: K051979
Trade/Device Name: ORS Endoscope Holder
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG
Dated: May 17, 2005
Received: August 3, 2005

Dear Mr. Smith:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Bucher
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051979

Device Name: ORS Endoscope Holder

Indications for Use:

The ORS 6000 Endoscope Holder is a single use disposable device as an accessory for ORS Solution Warmers. The ORS 6000 Endoscope Holder is designed to hold the optical end of various endoscopes above the warm solution to prevent fogging or wetting of the scope eyepiece.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brenn

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K051979