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SRS INTERNATIONAL CORPORATION

Suite 1000 • 1625 K Street, NW • Washington, DC 20006-1604
Telephone (202) 223-0157/0298 • Telecopy (202) 835-8970

OCT 31 1997

PREMARKET NOTIFICATION [510(K)] SUMMARY

1. Name/Address/Phone/Fax, Contact Person, Date:

Submitter's Name: SRS International Corporation
Address: 1625 K St., NW, Suite 1000 Washington, DC 20006
Telephone: 202-223-1057
Fax: 202-835-8970
Contact Person: Michael G. Farrow, Ph.D.
Date of Summary: February 8, 1997

2. Name of Device, Propietary Name, Common Name, Classification

Name of Device: Transcom Colon Hydrotherapy
Proprietary Name: Transcom Colon Hydrotherapy
Common Name: Colonic Irrigation System
Classification: Irrigator, Colonic (Gastro/Urology) 78 KPL

3. Legally Marketed Predicate Devices of Substantial Equivalence

Specialty Health Models A&B
Clearwater PPC-101
Doltolo Research Corp. Toxygen

4. Description of Device

This device is *not* a kit. This device is an instrument for hydrotherapy of the colon. It introduces filtered water at a confortable temperature into the large intestine. It is an automatic system for filling and emptying water into and out of the colon and thus cleansing the colon of its contents when medically indicated such as before radiological or endoscopic examination. It is hygienic, painless and odorless. The instrument has an automatic pressure safety system; automatic disinfection; a system for collection of samples for analysis; remote and frontal panel control; a counter for the number of liters of water used; a three-way faucet; flow regulator; thermostatic mixer and an automatic temperature safety feature. It contains disposable components for use only once in the therapy

5. Intended Use of Device

The indication for use of this device must be restricted to colon cleansing when medically indicated, such as before radiological or endoscopic examination.

6. Summary of Technological Characteristics Compared to Predicates

Summaries between Transcom and three predicates manufactured by Specialty Health, Clearwater, and Dotolo Research, appear below.

Differences in technological characteristics between Transcom and the predicate devices include the following.

Between Transcom and Specialty Health

1. Specialty Health uses a gravity flow system, Transcom a syringe.

Between Transcom and Clearwater

1. A sink and faucet are needed for the Clearwater unit; Transcom is plumbed.
2. Clearwater has no speculum collection; Transcom does.
3. Clearwater's unit is portable; Transcom is wall mounted
4. Clearwater uses a pump; Transcom uses a syringe

Between Transcom and Doltolo

1. Dotolo uses a gravity flow system, Transcom a syringe

Details in the technological characteristics for Transcom and the predicates are itemized on the following pages.

Parameter	*TRANSCOM*	*SPECIALTY HEALTH Hydro-San*	*CLEARWATER PPC-101*	*DOTOLO RESEARCH TOXYGEN*
Water Source	*Household/Commercial*	*Household/Commercial*	*Household/Commerical*	*Household/Commerical*
Water Flow (Pressure)	*Yes*	*Yes*	*Yes*	*Yes*
Water Flow Control Valve	*Yes*	*Yes*	*Yes*	*Yes*
Drainage System (Gravity)	*Yes*	*Yes*	*Yes*	*Yes*
Closed System				
Water	*Yes*	*Yes*	*Yes*	*Yes*
Drainage	*Yes*	*Yes*	*Yes*	*Yes*
Mixing Valve				
Grohemix	*Yes*	*Yes*	*Yes*	*Yes*
Powers Hydroguard	*N/A*		*Yes*	
Fittings				
Brass	*Yes*	*Yes*	*Yes*	*Yes*
Stainless	*Yes*	*Yes*	*Yes*	*Yes*
Cabinet Composition				
Stainless Steel	*Yes*	*N/A*	*Yes*	*N/A*
Sheet Metal (Painted)	*N/A*	*Yes*	*N/A*	*Yes*
Sink & Faucet	*N/A*	*N/A*	*Yes*	*N/A*
Cabinet Design	*Wall-Mount*	*Wall-Mount*	*Portable (on-wheels)*	*Wall-Mount*
Weight	*132.3 lbs.*	*Approx 40 lbs.*	*70 lbs.*	*Approx 40 lbs.*
Physical Dimensions	*1020 x 720 x 270 CM*	*20" w x 7" d x 20" h*	*19" w x 16" d x 41" h*	*20" w x 7" d x 20" h*
Pumps	*None*	*None*	*Sanitation System*	*None*

Parameter	*TRANSCOM*	*SPECIALTY HEALTH Hydro-San*	*CLEARWATER PPC-101*	*DOTOLO RESEARCH TOXYGEN*
Mode of Operation	*Continuous Water Flow* *Gravity Flow Drainage* *Manual Operation*	*Continuous Water Flow* *Gravity Flow Drainage* *Manual Operation*	*Continuous Water Flow* *Gravity Flow Drainage* *Manual Operation*	*Continuous Water Flow* *Gravity Flow Drainage* *Manual Operation*
Major Separate System Components	*Mixing Valve* *Pressure Regulator* *Water Manifold System* *Relief Valve System* *Monitoring System* *(Temp. Pressure)* *Viewing Assembly* *Sanitation System* *Lighting Assembly* *Drainage Assembly* *None*	*Mixing Valve* *Pressure Regulator* *Water Manifold System* *Relief Valve System* *Monitoring System* *(Temp. Pressure)* *Viewing Assembly* *Sanitation System* *Lighting Assembly* *Drainage Assembly* *None*	*Mixing Valve* *Pressure Regulator* *Water Manifold System* *Relief Valve System* *Monitering System* *(Temp. Pressure)* *Viewing Assembly* *Sanitation System* *Lighting Assembly* *Drainage Assembly* *Sink & Faucet*	*Mixing Valve* *Pressure Regulator* *Water Manifold System* *Relief Valve System* *Monitering System* *(Temp. Pressure)* *Viewing Assembly* *Sanitation System* *Lighting Assembly* *Drainage Assembly* *None*
Intended Usage	*Colonic Irrigator*	*Colonic Irrigator*	*Colonic Irrigator*	*Colonic Irrigator*
Monitoring Systems				
Water Temperature	*Yes*	*Yes*	*Yes*	*Yes*
Pressure	*Yes*	*Yes*	*Yes*	*Yes*
View Tube Assembly (Fluid Discharge Path)	*Yes*	*Yes*	*Yes*	*Yes*
Fluid Pathway	*Disinfected, and disposable except the view tube assembly which must be cleaned & sterilized prior to each procedure*	*Disinfected, and disposable except the view tube assembly which must be cleaned & sterilized prior to each procedure*	*Disinfected, and disposable except the view tube assembly which must be cleaned & sterilized prior to each procedure*	*Disinfected, and disposable except the view tube assembly which must be cleaned & sterilized prior to each procedure*
Specimum Collection	*Yes*	*Yes*	*No*	*Yes*

Parameter	*TRANSCOM*	*SPECIALTY HEALTH Hydro-San*	*CLEARWATER PPC-101*	*DOTOLO RESEARCH TOXYGEN*
Regulators (Water Pressure)	*Norgren Yes*	*Norgren Yes*	*Norgren Yes*	*Norgren Yes*
Relief Valve (Water Pressure)	*Norgren Yes*	*Norgren Yes*	*Norgren Yes*	*Norgren Yes*
Over Pressure Relief System	*Yes*	*Yes*	*Yes*	*Yes*
Systems Check Valves	*Yes*	*Yes*	*Yes*	*Yes*
Sanitation System Pump	*Yes Syringe*	*Yes Gravity Flow System*	*Yes Yes*	*Yes Gravity Flow System*
Gauges				
Water Temperature	*Yes*	*Yes*	*Yes*	*Yes*
Water Pressure	*Yes*	*Yes*	*Yes*	*Yes*
Electrical Requirements	*110/120 VAC 50/60 Hz service, power outlet to be grounded and polarized and GFI*	*110/120 VAC 50/60 Hz service, power outlet to be grounded and polarized and GFI*	*110/120 VAC 50/60 Hz service, power outlet to be grounded and polarized and GFI*	*110/120 VAC 50/60 Hz service, power outlet to be grounded and polarized and GFI*
View Tube Assembly Back Lighting	*Yes*	*Yes*	*Yes*	*Yes*

7. Non-Clinical Performance Data

Substantial equivalence is not based on an assessment of non-clinical performance data.

8. Clinical Performance Data

Substantial equivalence is not based on an assessment of clinical performance data.

9. Conclusions from Non-Clinical and Clinical

Not applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 1997

TRANSCQM Transcendencias Comerciales, S.L.
c/o Michael G. Farrow, Ph.D.
SRS International Corporation
1625 K Street, N.W.
Washington, D.C. 20006-1604

Re: K970482
TRANSCOM Colon Hydrotherapy Model HC-2000
Dated: September 10, 1997
Received: September 10, 1997
Regulatory class: II
21 CFR §876.5220/Product code: 78 KPL

Dear Dr. Farrow:

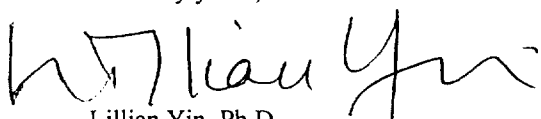
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4613. 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/dsmamain.html".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 970482

Device Name: TRANSCOM COLON HYDROTHERAPY MODEL HC-2000

Indications For Use:

The indication for use of this device must be restricted to colon cleansing when medically indicated, such as before radiological or endoscopic examination.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K970482

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)