FEB 1 5 2002

EXHIBIT 2

Sewoon Medical Device Corp. Ltd.
238-108, Yongdoo-dong Dongdaemoon-gu,
Seoul, KOREA
Telephone : 82-2-922-6555
Fax: 82-2-922-6558
Contact Person: Gil Whan Lee

September 10, 2001 Rev February 8, 2002

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: Sewoon All-silicone Foley Balloon Catheter. (Two way Three way, Radiopaque)
   Classification Name: Urological Catheter 78 EZL
   Common/Usual Name: Foley Balloon Catheter

2. Equivalent legally marketed device: All Silicone Foley Catheters, Rochester Medical Corp. K981612.

3. Indications for Use (intended use) For Urological Use only. Two-Way Catheter: Urethral catheterization for bladder drainage. Three -Way Catheter: Urethral catheterization for bladder drainage and bladder irrigation. Radiopaque Catheter: Urethral catheterization for bladder drainage with radiopaque substance for radiographic visualization.

4. Description of the Device: The Sewoon Medical Device Corp. Ltd. catheter has a tube with a single drainage eye on the proximal tip. The catheter has an additional eye for irrigation purposes. The catheters are available with a radiopaque option. The catheter is available in a combination of French sizes, capacities and lengths to accommodate pediatric and adult male and female applications. Available catheter lengths are 29 and 41 cm. French sizes from 6 to 26 and balloon sizes 1.5cc to 30cc.

5. Safety and Effectiveness, comparison to predicate device:

Element of Comparison	All Silicone Foley Catheters, Rochester Medical Corp. K 981612	ALL SILICONE FOLEY BALLOON CATHETER Sewoon Medical Corp., ltd
Intended Use	For urological only	For urological only (SAME)
Material	Silicone Elastomer	Silicone Elastomer (SAME)
Lumen	2 way, 3way	2 way, 3way (SAME)
Balloon size	2way: 1.5cc, 3cc, 5cc, 30cc 3 way: 5cc, 30cc	2 way: 1.5cc, 3cc, 5cc, 30cc (SAME) 3 way: 5cc, 30cc (SAME)
French size	2 way: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 24Fr, 26Fr 3 way: 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr	2 way: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr 24Fr, 26Fr 3 way: 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr (SAME)
Lengths available	"Male and Female Lengths" (Actual lengths not published)	SAME: 29 and 41 cm
Sterilization	ETO	SAME

6. Conclusion: In all respects, the All-Silicone Foley Balloon Catheters are substantially equivalent to one or more silicone balloon catheters that are legally marketed and/or were marketed prior to 1976. Testing and certifications demonstrate that the device meets the ASTM standard referenced above. All Silicone Foley Balloon catheters have been tested to and meet the following test requirements of ASTM F623-99 Standard Performance Specifications for Foley Catheters:

   Clause 4.1 " Flow Rate Through the Drainage Lumen"
   Clause 4.2 " Balloon Integrity, Resistance to Rupture
   Clause 4.3 " Inflated Balloon Response to pullout"
   Clause 4.4 "Balloon Volume Maintenance"
   Clause 4.5 "Balloon size and Shaft size"
   Clause 4.6 "Deflation Reliability"
   Clause 4.7 "Biocompatibility"

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 5 2002

Sewoon Medical Device Corp. Ltd.
c/o Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

Re: K013276
Trade/Device Name: All-Silicone Foley Balloon Catheter (Two way; Three way, Radiopaque)
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 EZL
Dated: December 24, 2001
Received: December 26, 2001

Dear Mr. Kamm:

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); 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

j) Indications for Use

510(k) Number K013276

Device Name: Sewoon Medical Device Corp. Ltd. All-Silicone Foley Balloon Catheter (Two Way; Three Way, Radiopaque)

Indications for Use:
For urological use only. Two-Way Catheter: Urethral catheterization for bladder drainage. Three -Way Catheter: Urethral catheterization for bladder drainage and bladder irrigation. Radiopaque Catheter: Urethral catheterization for bladder drainage with radiopaque substance for radiographic visualization

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

David G. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013276