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APR 2 8 2005

510(k) Summary

Date: Jan 31, 2005

1. Company and Submission Correspondent making the submission:

Name	Taewoong Medical Co., Ltd. 610 Ilsan-Technotown 1141-1 Backsuk-doing Ilsam-Ku, Koyang-si Kyunggi-do Korea	or	Correspondent (contract): Delphi Consulting Group 11874 South Evelyn Circle Houston, Texas 77071-3404
Telephone Contact	82-31-811-9111 J.H. Nam /Director		832-285-9423 J. Harvey Knauss

2. Device:

Proprietary Name:	Niti-S Esophageal Non-covered Stent & Introducer
Common Name:	Esophageal Stent
Classification Name:	Prosthesis, Esophageal
Classification:	21 CFR 878.3610
Product Code:	ESW

3. Predicate Device:

Ultraflex Esophageal NG Stent System,
Boston scientific Corp,
K032930

4. Description:

Niti-S Esophageal Non-covered Stent & Introducer is a rigid, flexible, and expandable tubular device made of a self-expanding Nickel Titanium alloy (Nitinol) wire that is intended to be implanted to restore the structure and/or function of the esophagus. This device also includes a device delivery system for deployment. Upon deployment, the stent imparts an outward radial force on the luminal surface of the lumen to establish patency.

5. Review:

The Niti-S Esophageal Non-covered Stent & Introducer has the similar device characteristics as the predicate device. Material, design and use concepts are similar.

The Niti-S Esophageal Non-covered Stent & Introducer has been subjected to extensive safety, performance, and validations prior to release. Safety and performance tests have been further performed to ensure the devices comply with applicable industry and US regulations.

6. Dimensions

Product	Art. No.	Stent					Introducer		
		Trunk		Head			Diameter (mm)	Usable Length (cm)	Total Length (cm)
		Diameter (mm)	Length (mm)	Diameter (mm)	Length(mm) R	Length(mm) L			
Niti-S Esophageal Non-covered Stent	E01606	16±0.32	30±0.6	24±0.48	15±0.3	15±0.3	5.3±0.1	70±7	95±9.5
	E01608		50±1.0						98±9.8
	E01610		70±1.4						101±10.1
	E01612		90±1.8						105±10.5
	E01615		120±2.4						107±10.7
	E01806	18±0.36	30±0.6	26±0.52					95±9.5
	E01808		50±1.0						98±9.8
	E01810		70±1.4						101±10.1
	E01812		90±1.8						105±10.5
	E01815		120±2.4						107±10.7

7. Indications For Use:

Niti-S Esophageal Non-covered Stent & Introducer is intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors.

8. Conclusions:

Niti-S Esophageal Non-covered Stent & Introducer is substantially equivalent to Ultraflex Esophageal NG Stent System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2005

TaeWoong Medical Co., Ltd.
c/o James Harvey Knauss
Contract Consultant
Delphi Consulting Group
11874 South Evelyn Circle
HOUSTON TX 77071

Re: K041648
Trade/Device Name: Niti-S Esophageal Non-Covered Stent(s) & Introducer
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: ESW
Dated: March 28, 2005
Received: March 31, 2005

Dear Mr. Knauss:

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

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

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

Indications for Use

510(k) Number (if known): K041648

Device Name: Niti-S Esophageal Non-covered Stent & Introducer

Indications For Use: Niti-S Esophageal Non-covered Stent & Introducer is intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors.

Prescription Use ✓ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041648