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SECTION II Summary and Certification

AUG 15 1997

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

Proprietary Device Name: CLIMBER - Partially Coated Guide Wire for Endoscopic Use

Classification Name: Accessories, Bite Blocks, for Endoscope

INTENDED USE

The CLIMBER - Partially Coated Guide Wire for Endoscopic Use is designed for endoscopic use. The CLIMBER is used for supporting cannulation or insertion into bile duct strictures and pancreatic duct strictures.

Note: This is the same intended use as the Terumo 450 cm Guide Wire for G.I. Use cleared under 510(k) K910722.

DESCRIPTION

The CLIMBER has a core of titanium nickel alloy coated with polyurethane. The distal tip up to 150 cm is coated again with polyurethane and then is coated with a hydrogel. The remaining 300 cm of the wire is coated with silicone. The wires are 450 cm in length and come in 0.035" diameter. The tip shape is available in straight or angled, shapeable; and straight or angled, non-shapeable.

SUBSTANTIAL EQUIVALENCE

The CLIMBER - Partially Coated Guide Wire for Endoscopic Use submitted in this 510(k) is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Terumo 450 cm Guide Wire for G.I. Use (K910722); the Microvasive GEENEN ENDOTORQUE™ Guide Wire; and the WILSON-COOK® TRACER™ WIRE GUIDE Slip-Coat™ Tip.

PRINCIPLE OF OPERATION/TECHNOLOGY

The CLIMBER - Partially Coated Guide Wire for Endoscopic Use is operated manually or by a manual process.

SECTION II Summary and Certification

DESIGN/MATERIALS

DESIGN/MATERIALS	CLIMBER	TERUMO 450 CM
Wire	Nickel-Titanium alloy coated w/polyurethane	Nickel-Titanium alloy coated w/polyurethane
Core Wire	single taper	single taper
Exterior Coating	hydrogel/silicone	hydrogel
SPECS		
Wire Diameter	0.035"	0.035"
Wire Length	450 cm	450 cm
Tip Configuration	straight/angled	straight/angled

PERFORMANCE

The performance of the Terumo CLIMBER - Partially Coated Guide Wire for Endoscopic Use is substantially equivalent to the performance of the cleared Microvasive GEENEN ENDOTORQUE™, the WILSON-COOK® TRACER™ and the Terumo 450 cm Guide Wire for G.I. Use (K910722).

The following tests were performed demonstrating the substantial equivalence of the Terumo CLIMBER submitted in this 510(k) to the Microvasive GEENEN ENDOTORQUE™ GUIDE WIRE, the WILSON-COOK® TRACER™ WIRE GUIDE Slip-Coat™ Tip and the Terumo 450 cm Guide Wire for G.I. Use.

- Butting Load
- Tip Flexibility Test
- Shaft Flexibility Test
- Memory Retention Test
- Shapeability Test
- Sliding Resistance
- Tensile Strength
- Torque Failure Test
- Torque Transmission Test

ADDITIONAL SAFETY INFORMATION

Sterilization conditions have been validated according to the European Standard, EN 550 (1994): Sterilization of Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization, to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Ethylene oxide residuals will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal register of June 23, 1978 (or as finalized or amended).

Manufacturing control test methods include: functional, extraction and sterility tests.

Blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." [External Communicating Devices, Blood Path Indirect, Limited Duration of Contact (<24 hours).] days). The blood contacting materials were found to be biocompatible.

The expiration dating for the CLIMBER - Partially Coated Guide wire for Endoscopic Use has been established to be 24 months.

CONCLUSION

The CLIMBER - Partially Coated Guide Wire for Endoscopic Use submitted in this 510(k) is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Terumo 450 cm Guide Wire for G.I. Use (K910722); the Microvasive GEENEN ENDOTORQUE™ Guide Wire; and the WILSON-COOK® TRACER™ WIRE GUIDE Slip-Coat™ Tip. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Date Prepared	May 22, 1997
Prepared by	Kristine Wagner Regulatory Affairs Specialist
Prepared for	Terumo Medical Corporation 125 Blue Ball Road Elkton, MD 21921 Phone (410) 392-7241 or (410) 392-7231 Fax (410) 398-6079

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 1997

Ms. Kristine Wagner
Regulatory Affairs Specialist
Terumo Medical Corporation
Regulatory Affairs Department
125 Blue Ball Road
Elkton, Maryland 21921

Re: K971937
CLIMBER - Partially Coated Guide Wire
for Endoscopic Use
Dated: May 23, 1997
Received: May 27, 1997
Regulatory Class: II
21 CFR §876.1500/Product Code: 78 KOG & FDT

Dear Ms. Wagner:

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,

William Yin

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 971937

Device Name: CLIMBER - Partially Coated Guide Wire for Endoscopic Use

Indications For Use:

The CLIMBER - Partially Coated Guide Wire for Endoscopic Use is designed for endoscopic use. The CLIMBER is used for supporting cannulation or insertion into bile duct strictures and pancreatic duct strictures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter D. Gallus

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971937

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

(Optional Format 1-2-96)