

K993695

APR 13 2000

LIGA-LOOP™ Suture Applicator
SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. **Submitter's name, address, telephone number, contact person, and date summary prepared;**
 - a. **Submitter:** HysteRx™, Inc.
32236-E Paseo Adelanto
San Juan Capistrano, CA 92675
(949) 488-8701
 - b. **Contact Person:** Judy F. Gordon, D.V.M.
Official Correspondent for HysteRx™, Inc.
ClinReg Consulting Services, Inc.
18732 Saginaw
Irvine, CA 92612
(949) 854-6314 (phone)
(949) 854-9652 (fax)
 - c. **Date Summary Prepared:** March 29, 2000
2. **Name of device, including trade name and classification name:**
 - a. **Trade/Proprietary Name:** LIGA-LOOP™ Suture Applicator
 - b. **Classification Name:** Instrument, Ligature Passing & Knot Tying
3. **Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:**
 - a. **Company:** Advanced Surgical, Inc.
Device: Endoscopic Ligation Device
510(k): K950126
Date Cleared: April 13, 1995
 - b. **Company:** Olympus Corporation
Device: Resectoscope Sheath
510(k): K931994/A

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Date Cleared: February 17, 1994

4. **A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

The LIGA-LOOP™ Suture Applicator is an instrument designed for ligation of soft tissue and blood vessels during surgical procedures. The device also incorporates a central lumen for use in irrigation, aspiration and/or imaging to increase patient safety during suturing. The LIGA-LOOP™ Suture Applicator contains similar materials, is of similar design, and has the same operating principle as the predicate devices.

5. **Statement of intended use:**

The LIGA-LOOP™ Suture Applicator is indicated for use in the ligation of soft tissue and blood vessels during open and guidance-assisted surgical procedures. The LIGA-LOOP Suture applicator with polyglycolic acid (PGA) suture and the LIGA-LOOP Suture Applicator with gut suture (plain and chromic) are intended for the same use, excluding cardiovascular and neurological procedures.

6. **Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.**

A comparison of the technological characteristics of the device and its predicate is shown in the following table:

Comparative Technological Characteristics

CHARACTERISTICS	LIGA-LOOP™ Suture Applicator HysteRx™, Inc.	Endoscopic Ligation Device Advanced Surgical	Resectoscope Sheath Olympus Corporation
Intended Use	For ligation of soft tissue and blood vessels during open and guidance-assisted surgical procedures For LIGA-LOOP with PGA or gut suture, cardiovascular and neurological procedures are excluded	For tying sutures around structures such as blood vessels and ducts during minimally invasive (laparoscopic) surgery	For insufflation, irrigation and aspiration
Operating Principle	Passes suture around targeted tissue and/or vessel using snare device to complete ligation No suture needles used. Central lumen provides for fluid management and/or imaging during suturing	Passes suture around targeted tissue and/or vessel using snare device to complete ligation No suture needles used.	Allows for fluid management during hysteroresection procedures
Performance Testing	Knot pull strength testing and diameter measurements of suture materials	Knot pull strength testing, diameter measurements of suture materials, ligation leakage testing	N/A
Handpiece and Tip Configuration:	Slide-type handpiece, J-shaped tip for grasping tissue and/or vessel	Stapler-type handpiece, with J-shaped tip for grasping tissue and/or vessel	N/A
Dimensions: Cannula (Fr):	Outer shaft is available in 2 sizes: 30 Fr and 39 Fr	Made to fit within 7, 10, 11, and 12 mm trocar cannulas	Outer diameter is 18.9 Fr to 28 Fr
Cannula Shaft Length (cm):	Available in 2 sizes, 12 cm and 24 cm	Unknown	N/A
Lumen Diameter (mm):	Irrigation/ Aspiration/ Imaging lumen is available in 2 sizes, 4.8 mm and 9 mm in diameter	N/A	Lumen diameter is 4-6 mm
Patient contact portion of device*	Outer Shaft, Jaws, Snare, and Suture	Outer Shaft, Functional Tip, Snare, and Suture	Sheath
Materials:			

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Handle	ABS	Stainless steel or aluminum	N/A
Outer shaft	Stainless steel	Stainless steel or aluminum	Stainless steel
Tips	Stainless steel, nitinol	Polycarbonate, stainless steel	Zirconium oxide ceramic
Suture Cartridge	N/A	Polycarbonate, stainless steel	N/A
Sutures	Plain gut, chromic gut, silk, PGA	Chromic Gut, silk, polypropylene	N/A
Potting	Epoxy	N/A	N/A
Central Lumen	Stainless steel	N/A	Stainless steel
Sterilization method	Gamma radiation, 25-40 kgy	Chromic gut and silk cartridges: gamma radiation; polypropylene:EO Handle: autoclave.	Unknown
Disposable/Reusable	Single use, disposable	Suture cartridges: single use, disposable Handle: reusable, autoclavable	Reusable

7. Brief summary of nonclinical tests and results:

The LIGA-LOOP™ Suture Applicator was tested to ensure that manipulation during installment of the suture to the applicator does not significantly affect suture diameter or knot pull-strength of the suture material. Test results indicate reliable performance when the device is used in accordance with the Instructions for Use. Manipulation of the suture material does not affect suture diameter or knot pull-strength. The LIGA-LOOP™ Suture Applicator does not raise any new safety, effectiveness, or performance issues.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

HysteRx™
c/o Judy F. Gordon, D.V.M.
ClinReg Consulting Services, Inc.
18732 Saginaw
Irvine, California 92612

Re: K993695
Trade Name: LIGA-LOOP™ Suture Applicator
Regulatory Class: II
Product Code: GAL, GAM, GAP, GEA
Dated: February 15, 2000
Received: February 17, 2000

Dear Dr. Gordon:

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.

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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) 594-4595. 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,



~~SCA~~ Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K993695

510(k) Number (if known): K993695

Device Name: LIGA-LOOP Suture Applicator

Indications for Use:

The LIGA-LOOP Suture Applicator is intended for use in the suturing of soft tissue and ligation of blood vessels during open and guidance-assisted surgical procedures. The LIGA-LOOP Suture Applicator with polyglycolic acid (PGA) suture and the LIGA-LOOP Suture Applicator with gut suture (plain and chromic) are intended for the same use, excluding cardiovascular and neurological procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vachner
(Signature)
Director of General Restorative Devices
Device Number K993695

Prescription Use

OR

Over-The-Counter Use
(Optional Format 1-2-96)