



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
Mr. Sigi Caron
Regulatory Manager
130 Forbes Boulevard
Mansfield, MA 02048

JUL 27 2015

Re: K991500
Trade/Device Name: Smith & Nephew Suture Lok
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW
Dated (Date on orig SE ltr): April 28, 1999
Received (Date on orig SE ltr): April 29, 1999

Dear Mr. Caron,

This letter corrects our substantially equivalent letter of July 14, 1999.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) Number (if Known):

Device Name: Smith & Nephew Suture Lok

Indications For Use:

The Smith & Nephew Suture Lok is indicated for use in open and endoscopic procedures, including thoracoscopic surgery, laparoscopic procedures and general surgery. This device is not indicated for use in contraception tubal ligation.

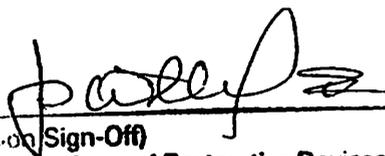
Intended Use:

The Smith & Nephew Suture Lok is intended for use in conjunction with USP size 0 2-0 and 3-0 Braided silk, nylon or polyester non-absorbable sutures in the management of soft vessel ligation and/or fixation of soft tissue structures during open and endoscopic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The-Counter Use _____
(per 21 CFR 801.109)



(Signature)
Division of General Restorative Devices
510(k) Number K941500

Section 7- 510k Summary

K991500

7.1 Statement This 510k summary is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

7.2 Submitter Smith and Nephew, Inc.
Endoscopy Division
130 Forbes Boulevard
Mansfield, Ma. 02048

7.3 Company Contact Sigi Caron
Regulatory Manager
(508) 261-3773

7.4 Device Name **Proprietary Name:** Smith & Nephew Suture Collet
Common Name:

- Suture Retention Device,
- Endoscopic Accessory,
- Laparoscopic Accessory

Classification Name:

- Suture Retention Device (79 KGS)
- Endoscopic accessories (78 GCJ)
- Laparoscopic accessories (85 HET)

7.5 Predicate Legally Marketed Devices

- Suture Collet
- Suture Lock
- Smith & Nephew and Acufex MIS Instruments

7.6 Device Description The Smith & Nephew Suture Lok comprises three main components:

- the suture Lok implant (ring and pin),
- the disposable cartridge assembly with threader, and
- the reusable delivery instrument.

7.7

Intended Use The Smith & Nephew Suture Lok is intended for use in the management of soft vessel ligation and/or fixation of soft tissue structures during open and endoscopic procedures.

7.8 Device Indications

The Smith & Nephew Lok is indicated for use in endoscopic procedures, including thoracoscopic surgery and laparoscopic procedures.

7.9 Substantial Equivalence

The Smith & Nephew Suture Lok is substantially equivalent to the Suture Collet, the Suture Lock, and braided silk, nylon or polyester 0, 2-0, and 3-0 suture. Comparative strength testing demonstrates the equivalence of the Suture Lok to the predicate devices.

The table below summarizes the similarities of the two devices. The similarities in design, materials, intended use, and indications for use between the Smith & Nephew Suture Lok and the predicate devices support the claim of substantial equivalence.

	Suture Lok	Suture Collet
<i>Implant:</i>		
Product Labeling	Sterile: Single Use Only	Sterile: Single Use Only
Materials	Implant grade polyacetal	Implant grade polyacetal
Indications	Open and Endoscopic/Laparoscopic/Thoracoscopic Surgical Procedures	Open and Arthroscopic Surgical Procedures
Indicated for use with	0, 2-0 and 3-0 braided silk, nylon or polyester sutures	2-0 silk monofilament sutures
Intended Use	Management of Soft Tissue	Management of Soft Tissue
Sterilization Method	Ethylene Oxide	Ethylene Oxide
<i>Delivery Instrument</i>		
Materials	Aluminum and Stainless Steel	Aluminum and Stainless Steel
Sterilization Method	Supplied non-sterile: must be sterilized prior to use via steam autoclave or ethylene oxide	Supplied non-sterile: must be sterilized prior to use via steam autoclave or ethylene oxide

Applicant _____

Date _____