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3. 510(k) Summary

JUL 1 8 2013

510(k) Summary
For neoClose Device

In accordance with 21 CFR **807.92** of the Federal Code of Regulations the following **510(k)** summary is submitted for the **neoClose Device**

510(k) Number	
Date Prepared	7 June 2013
Proprietary Name	neoClose Hasson and neoClose Universal
Common Name	Suture passer
Classification Name	§876.1500 Product code GCJ Endoscope and Accessories.
Device Classification	Class II
Device Panel	General and Plastic Surgery Devices
Predicate Device	neoClose (K123280)
Submitter	neoSurgical Ltd. Block 12 Galway Technology Park, Parkmore, Galway, Ireland Ph: +353 (0)91 421 000
Contact Person	Orla Brennan Block 12 Galway Technology Park, Parkmore, Galway, Ireland Ph: +353 (0)91 421 000

Device Description
The neoClose device is intended to facilitate the delivery of absorbable AutoAnchors through soft tissues of the body during endoscopic/ laparoscopic surgery. There are two neoClose product codes, neoClose Hasson and neoClose Universal, each consisting of an AccuGuide and two AutoAnchors loaded onto two Drivers.

The neoClose Hasson is designed to provide sealed anchoring of a laparoscopic trocar and suture placement for subsequent soft tissue approximation. The neoClose Universal is equivalent to the neoClose Hasson design in its method of soft tissue approximation but does not provide for sealed anchoring of a trocar. Soft tissue approximation is facilitated by delivering two AutoAnchors, through an AccuGuide with a Driver. The AutoAnchors and Drivers for both the neoClose Hasson and Universal are identical but the AccuGuides differ in construction. The Hasson AccuGuide features Suture Locks, a flexible Sleeve, and two Guide Channels while the Universal AccuGuide features a Thumb Grip and one Guide Channel.

Intended Use
The neoClose device is intended to facilitate the delivery of absorbable AutoAnchors through soft tissues of the body during endoscopic/ laparoscopic surgery.

Summary of Technological Characteristics of Modified Device Compared to the Legally Marketed Predicate Device
The technical characteristics of the applicant device are substantially equivalent to the predicate device with respect to indications for use, product design, materials, packaging, labeling and sterilization methods.

Support of Substantial Equivalence
neoSurgical has submitted information on indication for use, design and principle of operation, biocompatibility and performance characteristics to establish that the neoClose device is substantially equivalent to the currently marketed predicate device, neoClose (K123280). A detailed justification for substantial equivalence was completed which includes a side-by-side comparison of the product attributes of the applicant device and predicate device. Design Verification bench testing supports the performance of the neoClose device and demonstrates that it is at least as safe and effective as the predicate device, neoClose (K123280).

- Intended Use
  The neoClose components have the same intended use as the predicates.

- Physical Characteristics
  There are no technological differences between the neoClose device and the predicate devices (neoClose K123280) affecting intended use or safety and effectiveness.

- Anatomical Sites
  The neoClose device and its predicates may be utilized in the same anatomical site.

- Performance
  Design Verification bench testing support the use of the neoClose device and demonstrate that it is at least as safe and effective as the predicate device, neoClose (K123280).

- Safety Characteristics
  The GLP Animal Study completed with the predicate device demonstrates the safety and effectiveness of both the modified neoClose device and the predicate neoClose device (K123280), because an extension of shelf life is the only change to the design of the modified device. Design Verification bench testing also demonstrates that the modified device is at least as safe and effective as the predicate device, neoClose (K123280).

The neoClose device is substantially equivalent to the predicate device since it has the same intended use, does not raise new concerns regarding safety and effectiveness and is at least as safe and effective as the predicate device when used in accordance with the Instructions for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 18, 2013

neoSurgical, Limited
% Orla Brennan
Quality Assurance and Regulatory Affairs Director
Block 12 Galway Technology Park, Parkmore
Galway, Ireland

Re: K131688
Trade/Device Name: neoClose Hasson, neoClose Universal
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 07, 2013
Received: June 18, 2013

Dear Orla Brennan:

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" (21CFR 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,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use Statement

510(k) Number: K131688

Device Name: neoClose

Indications for Use: The neoClose device is intended to facilitate the delivery of absorbable AutoAnchors through soft tissues of the body during endoscopic/ laparoscopic surgery.

Prescription Use__X__ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131688