November 8, 2018

neoSurgical Ltd
% Ms. Orla Brennan
Quality Assurance & Regulatory Affairs Director
Block 12
Galway Technology Park
Parkmore
Galway, H91 E4YD Ireland

Re: K173917
Trade/Device Name: neoClose PDS Anchor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 26, 2018
Received: October 9, 2018

Dear Ms. 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173917

Device Name
neoClose PDS Anchor

Indications for Use *(Describe)*
neoClose® PDS is indicated for the approximation of soft tissue or prosthetic material during open or laparoscopic surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
For neoClose PDS Anchor

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

510(k) Number **K173917**

I. SUBMITTER

neoSurgical Ltd.
Block 12
Galway Technology Park,
Parkmore,
Galway, Ireland

Phone: +353 (0)91 421 000

Contact Person: Orla Brennan
Date Prepared: 01 December 2017

II. DEVICE

Name of Device: neoClose PDS Anchor
Common or Usual Name: Suture Passer
Classification Name: Endoscope and Accessories (21 CRF 876.1500)
Regulatory Class: II
Product Code: GCJ

III. PREDICATE DEVICE

1. Kumar T-Anchors Hernia Set (K081366)
2. neoClose (K142903)

IV. DEVICE DESCRIPTION

The neoClose PDS device consists of absorbable PDS Anchors and neoClose Drivers. The PDS Anchor consists of an absorbable PDS suture attached to an absorbable polymeric anchor. There are two distinct product codes: the neoClose PDS Anchor x 2 (NCPDSX2-U) and the neoClose PDS Anchor x 4 (NCPDSX4-U). The neoClose PDS Anchors and Drivers are provided sterile (EtO).

The neoClose PDS Anchors are pre-loaded on neoClose Drivers, which are passed through soft tissue for subsequent soft tissue or prosthetic material approximation.

V. INDICATIONS FOR USE

neoClose® PDS is indicated for the approximation of soft tissue or prosthetic material during open or laparoscopic surgical procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate devices are based on the following technological elements:

- Anchors are delivered into the abdominal cavity using a delivery device, and the sutures are tied to achieve approximation
- A delivery device is used to deliver the Anchor into the abdominal cavity

The following differences exist between the subject and predicate devices:

- A long-term absorbable suture has been introduced for the neoClose PDS Anchor. All other materials are identical to the neoClose predicate.

VII. 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 devices. The neoClose device components have the same intended use as the predicate devices identified. Results of testing have demonstrated that no adverse effects were introduced and the physical properties are appropriate for the intended use. *In Vitro* and *Ex Vivo* testing were completed.

VIII. CONCLUSIONS

The neoClose PDS Anchor is substantially equivalent to the predicate devices. It has the same intended use and does not raise new questions regarding safety or effectiveness. It is considered substantially equivalent in safety and effectiveness to the predicate device when used in accordance with the Instructions for Use.