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JUL 1 1 2013

Date prepared: 3-May-13

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Official Contact: James L. Vermeersch – President & CEO

Proprietary or Trade Name: Nexus™ Hemorrhoid Ligator

Common/Usual Name: Hemorrhoidal ligators

Classification Name/Code: 78 FHN – hemorrhoidal ligators
CFR 876.4400, Class II

Device: Multi-Ligator

Predicate Devices: K091519 – Haemoband – Multi-Ligator
K963166 – O'Regan – O'Regan Ligator

Device Description:
The inx Medical Nexus™ Hemorrhoid Ligator is a simple handheld device which allows the user to hold the hemorrhoid tissue with an applied suction while slipping a ligation band around the tissue.

The inx Medical Nexus™ Hemorrhoid Ligator is a disposable device for the rubber band ligation of hemorrhoids. It is for single use only and is supplied with preloaded non-latex rubber bands.

Indications for Use:
The inx Medical Nexus™ Hemorrhoid Ligator includes suction and ligation capabilities. The ligator is used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.

It is for use only by trained medical personnel located in hospitals, clinics, and doctors' offices.

Patient Population:
Individuals with hemorrhoids

Environment of Use:
Hospitals, clinics, and doctors' offices.

Contraindications
Do not use to treat:

- Anal polyps
- Grade IV hemorrhoids
- Patients with perineal infection

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- Patients with perineal Crohn's Dz
- Patients with portal hypertension
- Use with caution when treating patients on anticoagulants i.e. Warfarin

Predicate Device Comparison:

The inx Medical Nexus Hemorrhoid Ligator is viewed as substantially equivalent to the predicate devices because:

Indications –
- The ligator is used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.
- **Discussion** – The indications for use are identical to the predicates Haemoband Multi-Ligator (K091519) and O'Regan – O'Regan Ligator (K963166)

Technology and Mode of Operation –
- The internal mechanism for holding and banding the ligator bands is identical to the predicate Haemoband Multi-Ligator (K091519)
- The incorporation of an internal suction / vacuum source is equivalent to the predicate O'Regan – O'Regan Ligator (K963166)
- Mode of operation – that is banding hemorrhoidal tissue is identical to the predicates - Haemoband Multi-Ligator (K091519) and O'Regan – O'Regan Ligator (K963166)
- **Discussion** – The technology and mode operation are identical to the combined predicates.

Materials –
- The materials in patient contact are identical to predicate device Haemoband Multi-Ligator (K091519)
- **Discussion** – The materials are identical to the predicate.

Environment of Use –
- Identical to predicate – Haemoband Multi-Ligator (K091519) and O'Regan – O'Regan Ligator (K963166)
- **Discussion** – The environments of use are identical to the predicates.

Differences –
There are no differences between the predicates and the proposed device which would raise any new safety or risks and thus can be found to be substantially equivalent.

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	Proposed Device	Predicate Device	
510(k) Manufacturer		**K091519 Haemoband**	**K963166 O'Regan**
Device Name	**Nexus™ Hemorrhoid Ligator**	**Multi-Ligator**	**O'Regan Ligator**
Product Code	FHN	FHN	FHN
CFR	876.4400	876.4400	876.4400
Indications for Use	The inx Medical Nexus™ Hemorrhoid Ligator includes suction and ligation capabilities. The ligator is used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.	The Haemoband Multi-Ligator includes suction and ligation capabilities. The ligator is used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.	Hemorrhoidal ligators are used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.
Environment of Use	Hospitals, clinics, and doctors' offices.	Hospitals, clinics, and doctors' offices.	Hospitals, clinics, and doctors' offices.
Prescriptive	Yes, for use by trained medical personnel	Yes, for use by trained medical personnel	Yes, for use by trained medical personnel
Principle of Operation	Apply a ligature or elastic ring around the base of the hemorrhoidal nodule in order to cut off the blood flow to the hemorrhoidal tissue. Has an internal means to apply suction to hold the hemorrhoidal tissue prior to and during the ligature procedure. Pre-loaded bands in a pistol handgrip with trigger to apply suction and release the banding ring	Apply a ligature or elastic ring around the base of the hemorrhoidal nodule in order to cut off the blood flow to the hemorrhoidal tissue. Has a means to apply suction to hold the hemorrhoidal tissue prior to and during the ligature procedure. Pre-loaded bands in a pistol handgrip with trigger to apply suction and release the banding ring	Apply a ligature or elastic ring around the base of the hemorrhoidal nodule in order to cut off the blood flow to the hemorrhoidal tissue. Has a manual means to apply suction to hold the hemorrhoidal tissue prior to and during the ligature procedure.
Method of suction	Manually via an internal syringe type method to generate suction	Connected to an external vacuum source	Manually via a syringe type method to generate suction

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	Proposed Device	Predicate Device	
510(k) Manufacturer		**K091519 Haemoband**	**K963166 O'Regan**
Device Name	**Nexus™ Hemorrhoid Ligator**	**Multi-Ligator**	**O'Regan Ligator**
Procedure options	With or without the use of a proctoscope	With or without the use of a proctoscope	With or without the use of a proctoscope
Number of ligation bands pre-loaded	3-4	3-4	Not specified
Disposable	Single patient use, disposable	Single patient use, disposable	Single patient use, disposable
Material biocompatibility	Materials identical to K091519	Identified and cleared in K091519	N/A
Auto reload	Yes	Yes	No
Non-clinical Performance Testing	Environmental conditions Mechanical Drop test Ligator release and reload Vacuum / suction generated	Environmental conditions Mechanical Drop test Ligator release and reload	Vacuum / suction generated
Standards	None under section 514	None under section 514	None under section 514

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Non-clinical Testing Summary -

We have performed a number of tests appropriate for the proposed device. These tests include:

Drop

- Standard test method of free fall per ISO 60068-2-32
- Pass / fail criteria is that the device works
- **Discussion** – The proposed device passed the free fall testing.

Environmental (Hot / Cold / Humidity Exposure)

- Standard test methods for exposure followed the listed procedures
  - MIL-STD-810G Method 501.5, Procedure I - (60°C High Temperature Test Storage)
  - MIL-STD-810G Method 502.5, Procedure I - (-20°C Cold Temperature Test Storage)
  - MIL-STD-810G Method 506.5, Procedure I - (Humidity Test Storage)
- Pass / fail criteria was that they would meet the performance specifications.
- **Discussion** – The proposed device met the performance specifications after being exposed to the various conditions.

Biocompatibility of Materials –

- Materials are identical to the predicate Haemoband Multi-Ligator (K091519).
  - Parts which are Surface communicating, Mucosal contact, limited duration which would be Ligator components.
  - Parts which are Surface communicating, Mucosal contact, and prolonged duration would be the ligator bands.
- **Discussion** – All materials which are in patient contact are identical to the predicate Haemoband Multi-Ligator (K091519).

Suction Applied –

- Bench testing was performed to measure the applied vacuum generated by the device which was compared to the predicate O'Regan device.
- **Discussion** – The vacuum generated was determined to be equivalent to the predicate O'Regan – O'Regan Ligator (K963166).

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.

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 11, 2013

inx Medical
% Paul E. Dryden
President
ProMedic, Inc.
1819 Clarkson Rd., Suite #206
Chesterfield, MO 63017

Re: K131282
Trade/Device Name: Nexus™ Hemorrhoid Ligator
Regulation Number: 21 CFR§ 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: FHN
Dated: May 15, 2013
Received: May 16, 2013

Dear Paul E. Dryden:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Indications for Use Statement

510(k) Number: K131282 (To be assigned)

Device Name: Nexus™ Hemorrhoid Ligator

Indications for Use:

The inx Medical Nexus™ Hemorrhoid Ligator includes suction and ligation capabilities. The ligator is used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.

It is for use only by trained medical personnel in hospitals, clinics, and doctors' offices.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K131282