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

March 17, 2016

NELIS
% Mr. Peter Chung
Plus Global
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K152598
Trade/Device Name: Endo Keeper
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OTJ
Dated: January 15, 2016
Received: January 20, 2016

Dear Mr. Chung:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152598

Device Name
Endo Keeper

Indications for Use *(Describe)*
The Endo Keeper is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery.
This device is single use and sterilized.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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510(k) Summary

[as required by 807.92(c)]
K152598

1. Applicant

1) Company : NELIS
2) Address :1005, 201-Dong Bucheon Techno Park Ssangyong 3-cha Samjeong-dong Ojeong-gu, Bucheon-si Gyeongggi-do, 421-742 Korea
3) Tel : +82(32)624-1697,
4) Fax : +82(32)624-1699
5) Homepage : www.nelis.co.kr
6) In-charge : Director / Ryu Sung Soo / 82-10-4175-8558 / goriat2@naver.com
6) Contact person : Peter Chung / 412-512-8802 / peterchiung210@gmail.com
7) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
8) First prepared : Mar. 9, 2015
8) Submission date : Mar. 17, 2016
9) 510(k) number : K152598

2. Device Information

1) Trade Name : Endo Keeper
2) Common Name : Endoscopy Surgery Instrument
3) Classification Name : Laparoscopic Single Port Access Device
4) Product Code : OTJ
5) Regulation Number : 876.1500
6) Class of device : Class II
7) Panel : General & Plastic Surgery
8) Model type : 20 model codes including X-samll

3. The legally marketed predicate devices :

K141715 / Nelis / Glove Port

4. Device description :

The Endo Keeper is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery.
This device is single use and sterilized.

1) Model/type Name : 20 model codes including X-small

X-small	Small	Small-N	Small-S
Small-NS	Medium	Medium-N	Medium-S
Medium-NS	Large	Large-N	XX-Large
Small-NS-C	Small-NS-CG	Small-S-CG	Small-S-C
Medium-NS-CG	Medium-NS-C	Medium-S-C	Medium-S-CG

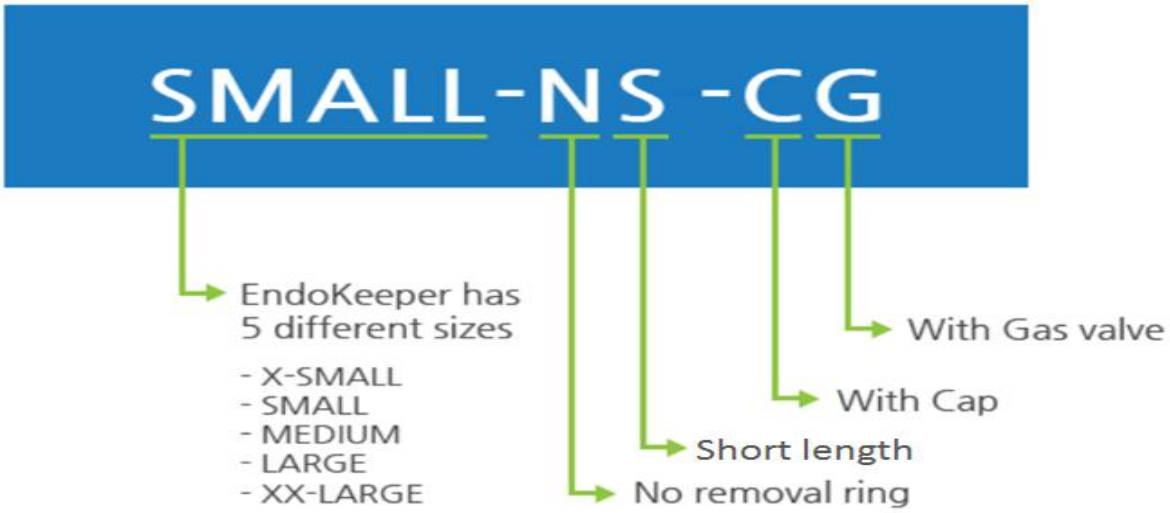
2) Model guide

① Main category

Size : XX-Large(195㎜) > Large(125㎜) > Medium(95㎜) > Small(60㎜) > X-small(41㎜)
The size is determined by “Insert ring” diameter.

② Classification

N : Remover ring and Remover ribbon or No Remover ring and Remover ribbon
C : Cap or No cap
G : Gas valve or No Gas valve
S : Length (185㎜), None “S”(195㎜)



③ Diameter of “Insert ring” and “Control ring”

Diameter of “Insert ring” and “Control ring”				
41mm	60mm	95mm	125mm	195mm
x-small	Small Small-N Small-S Small-NS Small-NS-C Small-NS-CG Small-S-C Small-S-CG	Medium Medium-N Medium-S Medium-NS Medium-NS-C Medium-NS-CG Medium-S-C Medium-S-CG	Large Large-N	XX-Large
← Small size of abdominal incision site			Large size of abdominal incision site →	
To selection of model according to size of incision site.				

④ Length of “Urethane forming Sheet”

Length of “Urethane forming Sheet”			
130mm	185mm	190mm	210mm
x-small	Small-S Small-S-C Small-S-CG Small-NS Small-NS-C Small-NS-CG Medium-S Medium-S-C Medium-S-CG Medium-NS Medium-NS-C Medium-NS-CG	Small Small-N Medium Medium-N Large Large-N	XX-Large
← Short length of abdominal wall		Long length of abdominal wall →	
To selection of model according to length of incision abdominal wall.			

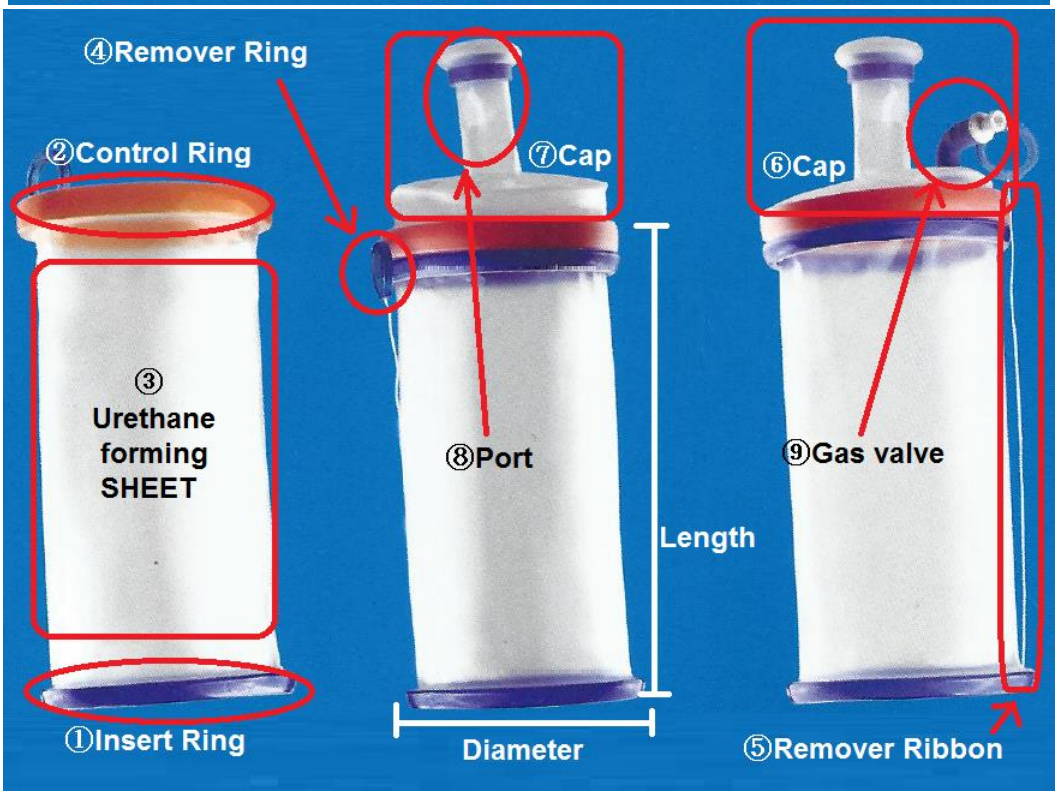
⑤ “Remover ring” and “Remover ribbon”

ex) 0000-**N**0-00 No “Remover ring (and Remover ribbon)”	
Applied model codes :	Small-N, Small-NS, Samll-NS-C, Small-NS-CG Medium-N, Medium-NS, Medium-NS-C, Medium-NS-CG Large-N
“Remover ring” and “Remover ribbon” are remove “Insert ring” out of body by pulling out the ring. It choose by end user (doctor).	

⑥ “Cap” and “Gas valve”

ex) 0000-00-**CG** C : with Cap G : with Gas valve	
Applied model codes :	
With Cap	Small-S-C, Small-NS-C Medium-S-C, Medium-NS-C
With Gas valve	Small-S-CG, Small-NS-CG Medium-S-CG, Medium-NS-CG
Cap : Protect the Gas Gas valve : It designed to inject the gas It choose by end user (doctor).	

2) Model design



No.	Part Name	Description
①	Insert Ring	Can fix this product by contacting tightly on the inner abdominal walls Can attach and detach on the inner abdominal walls by preventing this product from coming unstuck.
②	Control Ring	Can adjust the length of sheet and could be rolled up into the incision and can make various instrument inserted into the body like the way of “Insert ring”.
③	Urethane forming SHEET	Is made of polyurethane film and has a part of protrusion similar to a finger. It can wrap the incision and help various instruments to be inserted into the body. The part of protrusion similar to a finger is designed to protect the incision by wrapping. It helps to reduce the period of recovery after operation.
④	Remover Ring	Remove “Insert ring” out of body by pulling out the ring
⑤	Remover Ribbon	Connection between “Insert ring” and “Remover ring” for pulling out device
⑥	Cap	Protect to the Gas Applied to Endo Keeper CG model(including “Gas valve”)
⑦	Cap	Protect to the Gas Applied to Endo Keeper C model(except “Gas valve”)
⑧	Port	It designed to insert a medical instrument into a hole(diameter 5~12㎜). Applied to CG and C model
⑨	Gas valve	It designed to inject the gas.

3) Model measurement and classification

Name	Length	Diameter	Remover ribbon
X-small	130㎜	41㎜	N/A
Small	190㎜	60㎜	280㎜
Small-N			N/A
Small-S	185㎜	60㎜	280㎜
Small-NS			N/A
Medium	190㎜	95㎜	280㎜
Medium-N			N/A
Medium-S	185㎜	95㎜	280㎜
Medium-NS			N/A
Large	190㎜	125㎜	280㎜
Large-N			N/A
XX-Large	210㎜	195㎜	N/A
Small-NS-C	265㎜	60㎜	N/A
Small-NS-CG			
Small-S-C	265㎜	60㎜	280㎜
Small-S-CG			
Medium-NS-C	265㎜	95㎜	N/A
Medium-NS-CG			
Medium-S-C	265㎜	95㎜	280㎜
Medium-S-CG			

5. Intended Use :

The Endo Keeper is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery.

6. Technological characteristics :

The Endo Keeper is same intended use to Glove port (K141715). When compare with Glove port, it is same materials, structure and component.

The Endo Keeper is laparoscopic instrument port which retracts a small abdominal incision to allow multiple laparoscopic instruments to pass through to the abdomen.

The Urethane Forming Sheet (components of the Endo Keeper) function is to cover the incision site of abdominal.

When comparing Endo Keeper and Glove port(K141715), raw material is same of all components. (Used raw materials : Polyurethane, ABS, Nylon, Silicon)

Proposed device is similar components compared to Glove port (K141715).

(Same : Insert ring, Control ring, Urethane forming sheet, Cap, Gas valve, Remover ring and Remover ribbon. Except components of Opening ring and Extractioin pocket.)

7. Performance data:

Bench testing is performed to demonstrate the functionality and mechanical safety as following items

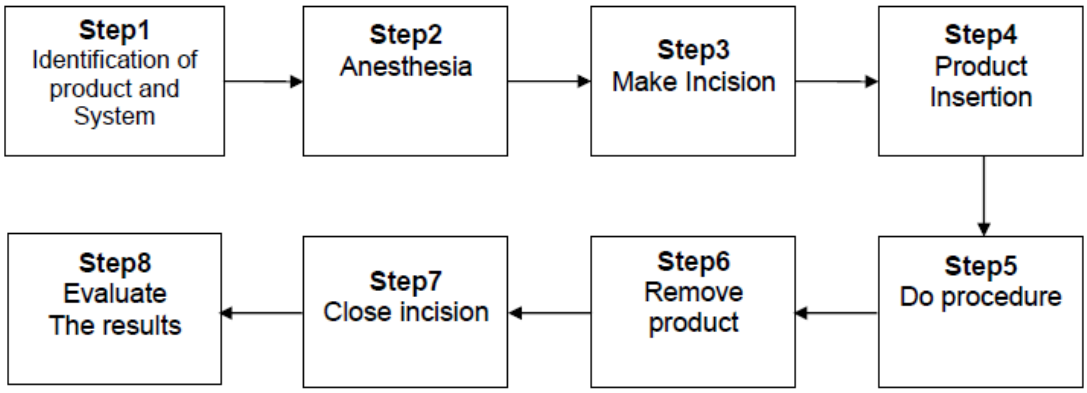
a. Comparative leak rate test
b. Tensile strength test
c. Insufflation flow rate test
d. Insertion-withdrawal forces of instrument test
e. Determination of minimum size of skin incision test
f. in-vivo test

Animal test

Varification of feasibility and functionality of Endo Keeper. The test results, there were no irritations and necrosis of the skin and fascia.

According to ISO 10993-2 and ISO 10993-1

Illustration 2. Test System



8. Predicate device comparison

Predicate device – Glove Port (K141715)

Proposed device and predicate device is manufactured by NELIS. The Endo Keeper have a identical intended use to the Glove Port in that they are indicated to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery. The components of the proposed device have identical appearance, fuction, purpose and material. Technical caracteristics is same of change of port during operation, gas leakage, abdominal wall inner clear visual field, installation in abdominal wall inner fixation and removal.

9. Conclusion:

The Device is investigated for function and effectiveness to compare the operation of function between Endo Keeper and predicate devices. Comparison results demonstrate that the specifications and performance of the device are same as functional and effective as the legally marketed predicate device.
Therefore, it is concluded that Endo Keeper is substantially equivalent to the legally marketed predicate device.

According to animal test results, the Endo Keeper is verified of feasibility and functionality. The test results, there were no irritations and necrosis of the skin and fascia. It can be possible to have a single incision during minimally invasive laparoscopic surgery.

The performance tests demonstrated that Endo Keeper is as safe, as effective and performs in a substantially equivalent manner to the predicate device.