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

February 24, 2017

3NT Medical Ltd.
% Ms. Orly Maor
Company Regulatory Consultant
25 A Sirkin Street
Kfar Saba 44421, Israel

Re: K162916
Trade/Device Name: 3NT Endoscopy System
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: January 25, 2017
Received: January 25, 2017

Dear Ms. Maor:

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,

Eric A. Mann -S

for Malvina Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat 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)*
K162916

Device Name
3NT Endoscopy System

Indications for Use *(Describe)*
The 3NT endoscopy system is intended to visualize the internal cavities of the ear, airways, nose and sinus cavities during diagnostic and therapeutic endoscope 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

3NTMEDICAL

Traditional Premarket Notification Submission – 510(k)

3NT endoscopy system

510(k) Number K162916

Date Prepared: January 25, 2017

I. SUBMITTER

3NT Medical Ltd.
22 Hamelacha Street,
PO Box 11384, Rosh Ha'ayin 4809169, Israel
Tel: +972.73.7154056
Fax: +972.73.7154058

Contact Person

Orly Maor
25A Sirkin Street
Kfar Saba 44421, Israel
Tel: +972-9-7453607
Fax: +972-153-9-7453607
oram.ma@gmail.com

II. DEVICE

Name of Device: 3NT endoscopy system
Common or Usual Name: 3NT endoscopy system
Classification Name: Nasopharyngoscope (flexible or rigid) and accessories (21 CFR 874.4760)
Regulatory Class: II
Product Code: EOB

III. PREDICATE DEVICE

3NT Medical Ltd. believes that the 3NT endoscopy system is substantially equivalent to the following predicate devices:

- Entellus Medical Inc. Flexible Endoscope and Eyepiece cleared under K082569.

- Vision-Sciences, Inc. Flexible Videoscope cleared under K072073.

IV. DEVICE DESCRIPTION

3NT endoscopy system is a single-use flexible ENT (ear, nose & throat) endoscope (provided sterile) which allows the user to steer through the anatomy and visualize it.

3NT endoscopy system includes:

1. A Single-use flexible endoscope (provided sterile) – includes a distal tip CMOS imager and an integrated working channel which allows irrigation through a single channel. It is the only part that comes in contact with the patient and is disposed of at the end of the procedure.
2. A Multi-use handle accessory (re-processible and auto-clavable) – engages the single-use endoscope component and allows the user to mechanically control its articulation through dedicated levers.
3. A Camera control unit (CCU) – includes a video processor and a white LED light source. The CCU includes an attachment cable which connects to the single-use endoscope, receives video images from the endoscope, and delivers LED light to the endoscope.

V. INDICATIONS FOR USE

The 3NT endoscopy system is intended to visualize the internal cavities of the ear, airways, nose and sinus cavities during diagnostic and therapeutic endoscope procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The 3NT endoscopy system has the same intended use as the predicate devices. Its indications for use are identical to that of the Entellus predicate and similar to that of the VSI predicate device. 3NT endoscopy system, same as the predicate devices, is a flexible endoscope which utilizes a visualization technology. All of 3NT flexible endoscope, VSI predicate device and Entellus predicate device provide a working channel which can be used for irrigation. Both 3NT flexible endoscope and the VSI predicate device can be articulated. In Entellus predicate device, the insertion tube can be inserted into an angulated cannula or catheter and assume its angulation and then advance and extend beyond the distal end of the cannula in the direction of the assumed angulation. By that, it is similar to the articulation of 3NT flexible endoscope. The dimensions of the 3 systems are comparable and all devices are advanced and articulated within the anatomy to observe it, under direct visualization. Similar tests and tests methods performed in accordance with the same standards

were used in both 3NT endoscope and the VSI predicate device to validate the design. The testing results showed that the minor differences in device characteristics and principles of operation between the subject device and predicate devices do not raise any new questions of safety or effectiveness.

The 3NT endoscopy system has the same technological characteristics as the predicate devices as demonstrated in the table below:

Item	**3NT Medical Endoscopy system**	**Entellus Medical Flexible Endoscope and Eyepiece**	**Vision-Sciences ENT-5000 and ENT-5100 Video ENT Scope with Endosheath**	**SE Justification**
Components Included	1. Flexible endoscope 2. Handle 3. CCU	1. Flexible glass fiberoptic endoscope 2. Eyepiece 3. Light post adaptor	1. Flexible endoscope 2. Handle 3. CCU (video processor)	Entellus does not include a video processor/camera, it is external to the system, but their core system still provides the same visualization functionality.
Imaging Technology	Distal tip sensor and digital video processor	Direct viewing fiberoptics or through a compatible video system (not included)	Distal tip sensor and digital video processor	Similar
Light Source	White LED light source at CCU	Not included	While LED light source at CCU	Same as VSI. Entellus uses an external Xenon light source, not part of their system
Field of View	90˚ (air)	>55˚ (air)	90˚ (air)	Same as VSI
Direction of View	Forward	Forward	Forward	Same

Item	3NT Medical Endoscopy system	Entellus Medical Flexible Endoscope and Eyepiece	Vision-Sciences ENT-5000 and ENT-5100 Video ENT Scope with Endosheath	SE Justification
Depth of Field	5-50mm	0-20mm	3-50mm	Similar; larger depth of field does not raise new questions because depth is at least as much as the predicates greater depth is not detrimental to performance.
Optimal working distance	5mm	Unknown	10mm	Similar
Insertion Tube Diameter	2.3mm	0.5mm	3.5mm	Similar to VSI. The 0.5mm of Entellus typically requires a sheath or cannula with total diameter comparable to 3NT and VSI.
Insertion Tube Working Length	120mm	128.5mm at 0.5mm diameter section.	280mm	Similar. The dimensions of the 3 systems are comparable
Articulation	125˚	Can bend by adhering to the shape of the cannula/sheath it is passed through, and bend to 140˚ or more	140˚ without sheath 125˚ with sheath	Similar
Working Channel	Yes, built-in	Yes, in a separable sheath or cannula. Not included	Yes, in a separable sheath (included)	Similar

Item	3NT Medical Endoscopy system	Entellus Medical Flexible Endoscope and Eyepiece	Vision-Sciences ENT-5000 and ENT-5100 Video ENT Scope with Endosheath	SE Justification
Scope Reusability	No, Single-use	Yes, Multiple-use	Yes, Multiple-use	3NT is a single use scope to be disposed after use thus it is not reprocessed, which presents less risk.

Based on the above analysis, 3NT Medical Ltd. believes that the 3NT flexible endoscope system is substantially equivalent to the legally marketed predicate devices

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

- **Risk analysis** per ISO 14971:2012
- **Biocompatibility testing**

  An evaluation of biocompatibility was performed in compliance with ISO 10993-1. Biocompatibility evaluation included cytotoxicity, irritation and sensitization testing. All tests were completed with passing results.
- **Sterilization, Packaging and Shelf Life Testing**

  Sterilization validation testing of the endoscope was performed to demonstrate compliance with ISO 11135-1. The handle was validated for cleaning and re-use by autoclave. In addition, shelf life and packaging testing were performed to support the labeled shelf life. All tests were successfully completed.
- **Bench Testing**

  Bench testing included the following:

Name of test	Test description
Endoscope Functionality and Simulated use	Endoscope functionality was tested to demonstrate device performance according to its intended use at simulated use conditions.
Endoscope Visual and Dimensions	Endoscope's dimensions, surface quality and weight were measured in accordance to ISO 8600 requirements and system specifications.
CCU functionality and Dimensions verification and Transportation	CCU dimensions, surface quality and weight and CCU functionality was

Name of test	Test description
	tested. Transportation and environmental conditions study was performed.
Optical performance	Optical performance of 3NT Endoscopy was tested in accordance with ISO 8600 requirements and system specification.
Endoscope Mechanical Properties	Mechanical properties of the single use endoscope were measured in accordance with system specification
Handle Functionality after reprocessing and Visual and Dimensions	Handle functionality and visual were tested after multiple reprocessing cycles. In addition, proper endoscope connection and disconnection to the handle and handle's levers operation were tested.
Endoscopy system image quality performance verification	Image quality performance of 3NT Endoscopy System was verified.
Endoscope Thermal characteristics	Endoscope's distal tip temperature was measured during system operation.

All tests met the predefined acceptance criteria.

- **Cadaver Study**

  Cadaver studies were performed by different users. Devices performed well to users' satisfaction. Users were able to access and visualize the entire nasal anatomic landmarks observable by current endoscopes. In particular, users were able to access and visualize the maxillary sinus, frontal sinus and sphenoid sinus, with minimal or no surgical manipulation. Device credibility was very good and users were satisfied by the image quality provided by the device. Irrigation functionality was tested and performed well.
  The test met the predefined acceptance criteria

- **Software Validation**

  Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.".

- **Electrical Safely and EMC**

  Electrical Safety per IEC 60601-1 and Electromagnetic compatibility (EMC) per IEC 60601-1-2 were conducted on the 3NT endoscopy system. In addition the system complies with IEC 60601-2-18.

VIII. CONCLUSIONS

The 3NT endoscopy system has the same intended use as the predicate devices. The principal features of the device that were described, as well as the testing provided, show that the minor differences in device characteristics between the subject device and predicate devices do not raise any new questions of safety or effectiveness.

Performance data and software validation has been provided, establishing that the 3NT endoscopy system performs as intended and in a manner that is substantially equivalent to the predicates.

Therefore, the device may be found substantially equivalent.