February 27, 2020

3NT Medical Ltd.
℅ Orly Maor
Consultant
Orly Maor
25A Sirkin Street
Kfar Saba, 4442156 Il

Re: K192305
Trade/Device Name: Colibri Endoscopy System
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: February 3, 2020
Received: February 3, 2020

Dear Orly 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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Michael J. Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

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)*
K192305

Device Name
Colibri Endoscopy System

Indications for Use *(Describe)*

Colibri 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)

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.

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:

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"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."

510(k) SUMMARY

3NT Medical Ltd.
Colibri Endoscopy System
K192305

1. SUBMITTER

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Date Prepared: February 25, 2020

2. DEVICE

Name of Device- Colibri Endoscopy System
Regulation Number- 21 CFR 874.4760
Regulation Name- Nasopharyngoscope (flexible or rigid) and accessories
Regulatory class- class II
Product Code- EOB
Classification Panel- Ear Nose and Throat

3. PREDICATE DEVICE

510(k) Number- K162916
Name of Device- 3NT Endoscopy System
Regulation Number- 21 CFR 874.4760
Regulation Name- Nasopharyngoscope (flexible or rigid) and accessories
Regulatory class- class II
Product Code- EOB
Classification Panel- Ear Nose and throat

4. DEVICE DESCRIPTION

The Colibri Endoscopy System is a single-use ENT (ear, nose & throat) endoscope (provided sterile under EtO sterilization) which allows the user to steer through the anatomy and visualize it.
The device is used in patients in whom endoscopic evaluation of, or intervention in, the ear, airways, nose, and sinus cavities is indicated.
The Colibri endoscopy system consists of:

- A Single-use Endoscope – includes a distal CMOS imager, an LED for illumination, and an add-on working channel which enables suction. The endoscope is provided sterile. The multi-use handle and the

endoscope attachment cable, which were separate components in the cleared 3NT Endoscopy System, are now an integral part of the single-use endoscope, thus eliminating all multi-use components from the system.

- A Video Console (formerly named Camera Control Unit, or CCU) which includes a video board and a tablet-based display, connects to the endoscope through the endoscope cable to receive video images from the endoscope and display them.

5. INDICATIONS FOR USE

The Colibri Endoscopy System is intended to visualize the internal cavities of the ear, airways, nose and sinus cavities during diagnostic and therapeutic endoscope procedures.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Ear, nose, and throat endoscopic visualization of the anatomy for diagnosis and therapeutic procedures is the technological principle for both the subject and predicate devices.

At a high level, the subject and predicate devices are based on the same technological elements:

- Endoscope – used to visualize the same target anatomies. The endoscope includes a suction/irrigation channel.
- Video console and Software – used to display the image received from the endoscope.

The changes from the cleared 3NT Endoscopy System include:

- Change in the Single use endoscope (size, shape electronics)
- Change in the Software (to support updated hardware)
- Adding an integrated tablet-based video display and user interface
- Package change- to accommodate the above modifications.

7. PERFORMANCE DATA

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

Biocompatibility testing

The biocompatibility evaluation for the Colibri Endoscopy System was conducted in accordance with ISO 10993-1: 2018 "Biological evaluation of medical devices" and the FDA guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Acute systemic toxicity

The Colibri Endoscopy System is categorized as:

According to nature of body contact – the Endoscope is considered surface contact device: devices that contact intact mucosal membranes.

According to duration of contact - the Endoscope is considered Limited Exposure A: devices whose cumulative single, multiple or repeated use or contact is up to 24 hours.

Test results verify that the Colibri Endoscopy System complies with the same biocompatibility requirements as the predicate device and hence substantial equivalence is determined.

Electrical safety and electromagnetic compatibility (EMC)
The Colibri Endoscopy System passed the electrical safety tests IEC 60601-1:2005/A1:2012 and IEC 60601-2-18:2009.
The electromagnetic compatibility of the Colibri Endoscopy System was tested per IEC60601-1-2:2014.

Test results verify that the Colibri Endoscopy System complies with the same electrical safety and EMC requirements as the predicate device and hence substantial equivalence is determined.

Software Verification and Validation testing
Software verification and validation testing were conducted and documentation was conducted in accordance with IEC 62304:20006 Medical device software – software life cycle processes and as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."
The Level of Concern of 3NT Console Software is defined as Moderate, as a failure or latent design flaw in 3NT console Software could not directly result in a serious injury as defined in the guidance, to the patient or operator and also, could not indirectly result in a serious injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Colibri Endoscopy System has the same level of concern as the predicate device and the software was validated following the same standard requirements and FDA guidelines, hence substantial equivalence is demonstrated.

Bench testing
The following tests were conducted with the Colibri Endoscopy System:

Test	Description	Results and Substantial Equivalence discussion
Colibri Scope Functionality and Simulated use, 3NT Console Functionality and dimensions verification	To ensure Colibri Endoscopy System functionality in simulated use is according to the indications for use.	The Colibri Endoscopy System passed all the functionality and simulated use tests. The tests passed and all acceptance criteria were met. The Colibri Endoscopy System and the predicate device have the same indications for use, which were verified by the described test. Substantial equivalence is demonstrated.
Colibri Scope Visual and Dimensions	To verify that the critical dimensions and surface quality of Colibri Scope comply with the predefined specification as part of the system requirements.	The Colibri Endoscopy System passed all the visual and dimensions inspections. The test passed and all acceptance criteria were met.
Colibri Scope Mechanical Properties Verification	To verify that the physical and mechanical properties of the Colibri Scope (tube flexibility Suction module disconnection mechanism, bond strength).	The tests passed and all acceptance criteria were met.
Colibri Scope System Image Quality Performance	A side by side comparison of image quality of Colibri Endoscopy System and predicate device was performed based on consensus international standards – '*CIE pub.116-1995 industrial color difference evaluation'* and published scientific literature 'Sharma Gaurav 2003 – *Digital Color Imaging Hand Book*'.	The Colibri Endoscopy System image is accurate and well reflects the observed items in terms of color accuracy. The tests passed and all acceptance criteria were met. The Colibri Endoscopy System image quality was found to be superior to that of the predicate device.

Test	Description	Results and Substantial Equivalence discussion
Colibri Scope Optical performance and MTF	A side by side comparison of Colibri and predicate device optical attributes was performed according to the requirements of ISO 8600 series and ISO 12233:2017.	The tests passed and all acceptance criteria were met. The Colibri Endoscopy System optical performance was found to be equal or better than these of the predicate device
Colibri Scope Labeling Verification and 3NT Console label verification	To verify Colibri Endoscopy System IFU and labels contain all required symbols, warnings, information, instructions for use and product specifications.	Colibri Labels and IFU found to include all information required by regulatory requirements and risks mitigations.
Transportation and Shelf life	Transportation simulation was performed according to ASTM D4169-16. Accelerated aging simulation was performed according to ASTM F1980-16.	The test passed and all acceptance criteria were met.
Joint connection test	To verify working channel tensile strength and no leakage under use conditions.	The tests passed and all acceptance criteria were met. Colibri Endoscopy System suction / irrigation channel was found to comply with no leakage and separation force requirements. This test verifies that no new risks of leakage or disconnection are introduced.

Conclusions

From the nonclinical tests that demonstrate that the device is as safe, as effective, and performs as well as the 3NT Endoscopy System we concluded that the Colibri Endoscopy System is substantially equivalent to the predicate device.