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

September 29, 2016

Nexcore Technology, LLC
% Olaf Teichert
Responsible Third Party Official
TUV SUD AMERICA, INC.
1775 Old Highway 8 NW
New Brighton, MN 55112-1891

Re: K162332
Trade/Device Name: Nexcore GI Insufflator
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FCX
Dated: August 30, 2016
Received: August 31, 2016

Dear Olaf Teichert,

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,

For Division

Douglas Silverstein -S
2016.09.29 14:07:51 -04'00'

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

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)*
K162332

Device Name
Nexcore GI Insufflator

Indications for Use *(Describe)*
The Nexcore GI Insufflator is designed to use CO2 as a distention media in the gastrointestinal tract when used in conjunction with a gastrointestinal endoscope.

The Nexcore GI Insufflator allows the physician to modulate and control the CO2 to the patient in an identical manner to that being done currently with room air which is supplied by an air pump in the light source of the endoscopic equipment.

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.

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NEXCORE TECHNOLOGY, LLC

510(k) Summary

Submitter: Nexcore Technology, LLC

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Waldwick, NJ 07463 USA

Submitter Contact: Milton Frank
CEO
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Telephone: 201-968-9400 x202
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Trade Name: Nexcore GI Insufflator

Common Name: Endoscopic Insufflator

Classification Name: Insufflator, automatic carbon-dioxide for endoscope

Product Code: FCX

Regulatory Class: II

Regulation Number: 21 CFR Part 876.1500

Classification Panel: Gastroenterology and Urology

Date Prepared: July 21, 2016

Predicate Device: Bracco CO2MPACT Endoscopic Insufflator (P/N: 710300)

Predicate 510(k) Number: K111648

Device Description:

The Nexcore GI Insufflator is designed to use CO_2 as a distention media in the gastrointestinal tract when used in conjunction with a gastrointestinal endoscope.

The Nexcore GI Insufflator is a reusable electronic medical device that delivers CO_2, via a gastrointestinal (GI) endoscope, to provide improved visualization, increase patient comfort, and increase procedure efficiency during GI endoscopic procedures. The insufflator operates by receiving CO_2 from a pressurized cylinder or hospital infrastructure supply and regulating it down in stages to a lower pressure by means of primary and secondary regulators. Each stage of pressure, including the output pressure, has a pressure relief valve as a redundant safety backup for the regulator system. The flow rate is controlled by an electronically controlled proportional valve, which utilizes differential pressure across an in-line orifice to measure flow rate. The output flow rate is user adjustable with four pre-defined settings: high, medium, low and ultra-low.

The device contains software that receives inputs from a touchscreen user interface and controls the operation of the device, including the delivery of CO_2 to the endoscope. There are no direct patient-contacting components in this device, other than the delivered CO_2 gas. The device is reusable and is not sterile. The Nexcore GI Insufflator is used in hospitals and outpatient endoscopy suites. The device operates from mains power.

There is one model (NX-350) of this device. The accessories sold with the device are the line (power) cord and a pin-indexed high pressure hose for CO_2 cylinder connection.

The Nexcore GI Insufflator is used with commercially available, separately cleared devices, including a GI endoscope and tube set. The appropriate compatible tube set is intended to provide CO_2 or air (if CO_2 is not used) to an endoscope for endoscopic procedures and must have a $\leq$0.2 micron hydrophobic filter, check valve, and luer fittings at both ends. The tubing ID must be sufficient to deliver 4L/min.

Intended Use:

The Nexcore GI Insufflator is designed to use CO_2 as a distention media in the gastrointestinal tract when used in conjunction with a gastrointestinal endoscope.

The Nexcore GI Insufflator allows the physician to modulate and control the CO_2 to the patient in an identical manner to that being done currently with room air which is supplied by an air pump in the light source of the endoscopic equipment.

Comparison to Predicate Device

The proposed and predicate devices have identical intended uses and identical principles of operation. The fundamental technological characteristics of the two devices are the same. Both are electronic medical devices that take in CO_2 from a pressurized gas source and meter it to a tube set and GI endoscope in a controlled fashion. The proposed and predicate devices have substantially equivalent specifications, with only minor differences in a few specifications that do not raise different questions of safety and

effectiveness. Performance data demonstrate that the proposed device is safe and effective.

Many aspects of the designs were compared including: biocompatibility, inlet mains power, hose sets, inlet pressure, outlet pressure, outlet overpressure, selectable flow rates, selectable shutdown times, form factor and gas supply configurations. All aspects are fundamentally equivalent, with only minor differences.

The minor differences between the proposed and the predicate devices include:

- The Nexcore GI Insufflator has a staged/redundant overpressure method as follows: an audible alarm with on-screen alert at 7.5psi; shutdown switch activated at 8psi; mechanical relief valve opens at 10psi. The predicate device has a mechanical relief valve that opens at 7.25psi. The Nexcore GI Insufflator limits output pressure to 5psi, by controlling flow rate. In order for these overpressure devices to react, the system would have to be in a fault mode where the 5psi limit is not functioning.
- The Nexcore GI Insufflator offers an "Ultra-Low" flow rate setting. The predicate device does not offer an "Ultra-Low" flow rate setting. The Ultra-Low setting was added to address market needs.
- The Nexcore GI Insufflator offers an intermediate 90 minute timer. The predicate device does not offer an intermediate 90 minute timer. The 90 minute setting was added to address market needs.

The proposed and predicate devices are substantially equivalent.

Summary of Non-Clinical Testing

Performance (Bench) Testing

Non-clinical testing was performed on the Nexcore GI Insufflator. The purpose of the testing was to compare the output the predicate device against the Nexcore GI Insufflator. Follow up non-clinical testing was performed to further focus and define the software's control algorithms. This testing also included a distal pressure test. This was conducted to ensure the maximum delivered pressure does not exceed average anatomical maximum pressure for the GI tract.

In summary, the non-clinical testing proved equivalent performance to the existing FDA cleared product along with delivered pressure not exceeding maximum anatomical pressures. The Nexcore GI Insufflator meets its design inputs.

Software Testing

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." The software for this device was considered as a "moderate" level of concern, since a non-mitigated failure or latent flaw in the software could result in minor injury to the patient, perforated colon.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing

Electrical safety and EMC testing were conducted on Nexcore GI Insufflator. The device complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

Biocompatibility

A biocompatibility evaluation was conducted on Nexcore GI Insufflator in comparison to a 510(k)-cleared reference device, the Xylog Insufflator (K945970). Based on this evaluation, the device complies with ISO 10993-1 for biocompatibility.

Standards Applied

The following standards were applied to the development and design of the Nexcore GI Insufflator:

Standard Code	Date Code	Edition/ Revision	Description
IEC 60601-1	08-2012	3.1	Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
EN 60601-1-2	03-2007	3.0	Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Electromagnetic Disturbances- Requirements and Tests
IEC 60601-1-8	11-2012	2.1	Medical Electrical Equipment Part 1-8: General Requirements for Basic Safety and Essential Performance- Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems
AAMI/ANSI/IEC 62304	05-2006	1.0	Medical Device Software- Software Life Cycle Processes
ISO 14971	07-2012	2012	Medical Devices- Application of Risk Management to Medical Devices
IEC 62366-1	02-2015	1.0	Medical Devices- Part 1: Application of Usability Engineering to Medical Devices (General 1 (QS/RM))

AAMI/ANSI/ISO 10993-1	10-2009	2009 (R) 2013	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process

Conclusion

Non-clinical verification and validation activities were conducted to establish the performance and safety characteristics of the Nexcore GI Insufflator**.** The results of these activities demonstrate that the Nexcore GI Insufflator is safe and effective when used in accordance with its intended use and labeling. The Nexcore GI Insufflator has the same intended use and the same fundamental technological characteristics as the predicate device. The minor differences between the proposed and predicate devices do not raise different questions of safety and effectiveness. Performance data demonstrate that the proposed device is safe and effective. Therefore, the Nexcore GI Insufflator is considered substantially equivalent to the predicate device.