November 27, 2024

Nextbiomedical Co., Ltd.
℅ Gali Shrieber
Senior Regulatory Affairs Specialist
Covidien llc.
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K240994
Trade/Device Name: Nexpowder™
Regulation Number: 21 CFR 878.4456
Regulation Name: Hemostatic Device For Intraluminal Gastrointestinal Use
Regulatory Class: Class II
Product Code: QAU
Dated: April 11, 2024
Received: October 28, 2024

Dear Gali Shrieber:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2024.11.27 10:36:14 -05'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240994

Device Name
Nexpowder™

Indications for Use *(Describe)*
Nexpowder™ is used for hemostasis of nonvariceal gastrointestinal bleeding.

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.

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510(k) SUMMARY (K240994)

NextBiomedical CO., LTD.

Nexpowder™

I. SUBMITTER

Submitter Name and Address:	NEXTBIOMEDICAL CO., LTD. 6 Venture-ro 100 beon-gil, Yeonsu-gu Incheon, 22013 Republic of Korea
Correspondent Information:	Covidien llc. 15 Hampshire Street MA, 02048 USA
Contact person:	Gali Shrieber Senior Regulatory Affairs Specialist gali.shrieber@medtronic.com
Phone:	972-73-2501577
Date prepared:	November 26, 2024

II. DEVICE

Name of Device:	Nexpowder
Device Common Name:	Hemostatic Device For Endoscopic Gastrointestinal Use
Classification:	Class II Regulation 21 CFR 878.4456 Hemostatic device for intraluminal gastrointestinal use Product Code: QAU

III. PREDICATE DEVICE(S)

Hemospray® Endoscopic Hemostat (DEN170015) - Predicate device

Nexpowder (K202929) - Reference device

IV. DEVICE DESCRIPTION

The Nexpowder is used for hemostasis of non-variceal gastrointestinal bleeding. It is a prescription only, single-use device provided with a powder pre-packaged in a vial, and a delivery system, which consists of a spray body, a connector and a delivery catheter. The catheter is inserted through an endoscope's working channel to deliver the powder to the intended hemostasis target site. Nexpowder is almost identical to the currently marketed device (K202929) and has the same technological characteristics and mechanism of action, but differs in the indications for use, where the subject device is also indicated for lower GI bleeding.

V. INDICATIONS FOR USE

Nexpowder is used for hemostasis of nonvariceal gastrointestinal bleeding.

VI. TECHNOLOGICAL CHARACTERISTICS

	Subject Device Nexpowder	**Predicate Device Hemospray Endoscopic Hemostat (DEN170015)**	**Reference Device Nexpowder (K202929)**	**Comparison**
Indications for Use	Nexpowder is used for hemostasis of non-variceal gastrointestinal bleeding	The COOK Hemospray Endoscopic Hemostat is used for hemostasis of non-variceal gastrointestinal bleeding	Nexpowder is used for hemostasis of non-variceal, upper gastrointestinal bleeding	Identical to predicate device
Device main components	Hemostatic powder agent and a delivery system	Hemostatic powder agent and a delivery system	Hemostatic powder agent and a delivery system	Identical

	Subject Device Nexpowder	Predicate Device Hemospray Endoscopic Hemostat (DEN170015)	Reference Device Nexpowder (K202929)	Comparison
Operation principle	The powder is delivered by use of a delivery system and through a catheter inserted through the working channel of an endoscope which provides access to the site of the bleeding	The powder is delivered by use of a delivery system and through a catheter inserted through the working channel of an endoscope which provides access to the site of the bleeding	The powder is delivered by use of a delivery system and through a catheter inserted through the working channel of an endoscope which provides access to the site of the bleeding	Identical
Powder main chemical composition	• Succinic anhydride (ε-poly-L-lysine) • Aldehyded dextran	• Sodium bentonite	• Succinic anhydride (ε-poly-L-lysine) • Aldehyded dextran	Different from predicate device
Delivery method	Powder propelled by battery power	Powder propelled by CO_2	Powder propelled by battery power	Different from predicate device

Nexpowder and the primary predicate

Nexpowder and Hemospray (DEN170015) have similar technological characteristics and mechanism of action. In both devices, the powder is delivered using a delivery system and a catheter inserted through the working channel of an endoscope, allowing access to the targeted site for hemostasis.

The main difference in technological characteristics is the composition of the hemostatic powder. Nexpowder contains mainly Aldehyded Dextran and Poly-L-Lysine (Polysaccharide), while the predicate is composed of proprietary components and bentonite powder. Even though the hemostatic agent of Nexpowder differs from the predicate device in chemical composition, it does not raise different questions of safety and effectiveness.

In terms of Principles of operation, Nexpowder and the predicate device, Hemospray, differ in the delivery method and energy source that provides the physical force to move the hemostatic powder agent into the delivery catheter.

The Hemospray includes a handle with a pressurized CO_2 cartridge and the powder is propelled through the catheter by release of CO_2 from the cartridge located in the device.

The Nexpowder hemostatic agent is deployed by insoluble air propellant. It utilizes a pre-installed battery as its power source, allowing air pressure generated from the air pump in the delivery system's spray body to provide effective physical force to move the powder into the delivery catheter.

The air-powered mechanism of Nexpowder results in low-pressure, controlled delivery of material with minimal particle scattering or loss of visualization. Other than the air pressure itself, no mechanical force or direct contact is made with the target hemostasis site during the delivery process of Nexpowder.

Nexpowder and reference device

Nexpowder is technologically identical to the reference device (Nexpowder cleared in K202929). The overall design, materials, chemical composition, and energy source of Nexpowder have not been modified since cleared by the agency.

The only difference from the cleared device is the expansion of indications to the lower GI and several minor device modifications that were assessed by the company and determined to not significantly affect the safety or efficacy of the device.

VII. PERFORMANCE DATA

The company collected clinical data outside the United States (OUS) in support of the lower GI indication expansion. Clinical data was gathered from a prospective study and retrospective studies conducted in Korea, in addition to aggregated data collected in the European Union (EU). A total sample size of 260 lower GI cases were collected and analyzed. Results were compared to the predicate device- Hemospray. The results of Nexpowder were found to be comparable with that of Hemospray as presented in its De-Novo authorization (DEN170015), further supporting Nexpowder indication expansion to the lower GI.

All other pre-clinical testing in support of Nexpowder was leveraged from the previously cleared Nexpowder device, cleared under K202929.

VIII. CONCLUSIONS

Nexpowder has the same intended use and indications for use as the predicate device- Hemospray (DEN170015). The two devices differ in the powder chemical characteristics, delivery method and energy source, but those differences do not raise different questions of safety and effectiveness, as the safety and effectiveness of Nexpowder powder and device design were already established in K202929.

The Nexpowder has the same intended use, technological characteristics, and principles of operation as its reference device (K202929). The expanded indication does not alter the intended use of the device. The safety and effectiveness of the device in the lower GI was established by clinical data and is further supported by comparing Nexpowder data to that of the predicate device, Hemospray, already cleared for the lower GI.