September 16, 2022

Nextbiomedical Co., Ltd.
℅ Kyungyoon Kang
CEO
K-Bio Solutions
201 South 4th St, Suite 727
San Jose, California 95112

Re: K202929
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: September 24, 2020
Received: September 29, 2020

Dear Kyungyoon Kang:

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 Deborah Fellhauer, RN, BSN
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202929

Device Name
Nexpowder™

Indications for Use *(Describe)*
Nexpowder™ is used for hemostasis of non-variceal, upper 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.

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510(k) Summary: Nexpowder™

I. Applicant/Manufacturer Information

Type of 510(k) Submission: Traditional 510(k) Premarket Notification

Applicant's Information
Name of Sponsor: NEXTBIOMEDICAL CO., LTD.
Address: 6, Venture-ro 100beon-gil, Yeounsu-gu, Incheon, Republic of Korea
Contact Name: Eunhye Lee
Telephone No.: 82-32-880-0820
Email Address: ehlee@nextbiomedical.co.kr

Correspondent's Information
Company Name: K-Bio Solutions
Correspondent Name: Mr. Kyungyoon Kang
Email Address: kyungyoon.kang@kbiotechsolutions.com

Date Prepared: September 9th, 2022

II. Regulatory Information

Proposed Device:

- Trade/Proprietary Name: Nexpowder™
- Classification Name: Hemostatic device for intraluminal gastrointestinal use
- Regulatory Class: Class II, Regulation Number: 878.4456,
- Product Code: QAU
- 510(K) number: K202929

Predicate Device:

- Trade/Proprietary Name: Hemospray® Endoscopic Hemostat
- Classification Name: Hemostatic device for intraluminal gastrointestinal use
- Product Code: QAU
- De Novo Clearance number: DEN170015
- 510k Submitter: Wilson-Cook Medical, Inc.

Reference Device:

- Trade/Proprietary Name: PerClot® Topical
- Classification Name: Dressing, Wound, Drug
- Product Code: FRO
- 510(K) number: K132105
- 510k Submitter: CRYOLIFE, INC.

III. Device Description of the Nexpowder™

The Nexpowder™ is used for hemostasis of non-variceal, upper gastrointestinal bleeding. The Nexpowder™ is a prescription only, single-use device provided with a pre-packaged powder, a vial, and a Delivery System, which consists of a Spray body, a Connector and a Delivery Catheter. The powder vials

are provided in a sterile condition with gamma radiation sterilization and the non-sterile external Spray Body delivery system with its sterile Connector and sterile Delivery Catheter.

The hemostatic powder agents of the Nexpowder™ are primarily composed of succinic anhydride (ε-poly-L-lysine) and oxidized dextran and are endoscopically applied through a catheter channel of the delivery system to control gastrointestinal bleeding in the upper gastrointestinal tract. Utilizing the installed battery power, air pressures are generated from the air pump placed in the spray body of Nexpowder™ delivery system to provide effective physical force to move the hemostatic powder agent into the delivery catheter. The hemostatic agents of the Nexpowder™ ultimately get sprayed onto the hemostasis target site in the gastrointestinal tract. Nexpowder is excreted from the patient's gastrointestinal or digestive system primarily by peristalsis of the human digestive system within the three days.

IV. Intended Use/ Indications for Use

Nexpowder™ is used for hemostasis of non-variceal, upper gastrointestinal bleeding.

V. Substantial Equivalence Comparison with Predicate Device

Assessment Table of Substantial Equivalence

Comparison Item	Proposed Device	Predicate Device	Assessment of Substantial Equivalence
Trade/Device Name	Nexpowder™	Hemospray® Endoscopic Hemostat	N/A
Common Name	Hemostatic Device for intraluminal gastrointestinal use	Hemostatic Device for intraluminal gastrointestinal use	Identical to the predicate device
510k Number	K202929	DEN170015	N/A
Manufacturer	NEXTBIOMEDICAL Co., Ltd	Wilson-Cook Medical, Inc.	N/A
Application/ Device Overview	The device is applied by using catheter, delivery system and a gastrointestinal endoscope. The device is comprised of a handheld delivery system that propels hemostatic powder through a catheter to the GI bleeding site.	The device is applied by using endoscopic catheter, delivery system and a gastrointestinal endoscope. The device is comprised of a handheld delivery system that propels hemostatic powder through a catheter to the GI bleeding site.	Similar to the predicate device

Intended Use / Indications for Use	The device is intended to be used for hemostasis of non-variceal, upper gastrointestinal bleeding.	The device is intended to be used for hemostasis of non-variceal gastrointestinal bleeding.	The indications for use are a subset of the indications cleared for the predicate device.
Operation Principle	When the device comes in contact with an actively bleeding site, the powder absorbs water, then acts both cohesively and adhesively, forming a mechanical barrier over the bleeding site.	When the device comes in contact with an actively bleeding site, the powder absorbs water, then acts both cohesively and adhesively, forming a mechanical barrier over the bleeding site.	Similar to the predicate device
	Nexpowder is an inert powder developed for endoscopic hemostasis. The powder is delivered by use of a battery powered delivery system and through a catheter inserted through the working channel of an endoscope which provides access to the site of the bleed. It contains no human or animal proteins or botanicals	Hemospray is an inert powder developed for endoscopic hemostasis. The powder is delivered by use of a carbon dioxide powered delivery system and through a catheter inserted through the working channel of an endoscope which provides access to the site of the bleed. It contains no human or animal proteins or botanicals and has no known allergens.	Similar to the predicate device, as for the difference in the delivery system that Nexpowder™ is operated based on the battery powered delivery system, while the predicate, Hemospray® is operated based on the aerosol delivery system does not raise different questions in terms of safety and effectiveness, given Nexpowder™ delivery system has been verified to meet the electrical safety and performance requirements per the FDA's recognized standards of IEC 60601-1, IEC 60601-1-2, and IEC 60601-1-6 and special controls. The same FDA's recognized IEC standards have been applied for the electrical safety and performance evaluation of the predicate, Hemospray Endoscopic Hemostat (DEN170015, Wilson-Cook Medical, Inc.).
Product Design	The device system consists of hemostatic powder agent and a delivery system.	The device system consists of hemostatic powder agent and a delivery system.	The overall device system with hemostatic agent and delivery system is substantially equivalent/similar to the predicate device in terms of the use of hemostatic agent and a delivery

			system under gastrointestinal endoscopy.
Hemostatic Agent	Powder in a vial, including: • ε-poly-L-lysine • Aldehyded dextran • Polyvinylpyrrolidone • Brilliant Blue FCF • Low-substituted Hydroxypropylcellulose L-HPC • Lactose Monohydrate • Magnesium Stearate	Sodium bentonite	The composition of the hemostatic powder components of the subject and predicate devices is different.
Specifications	Catheter French size: 7.5Fr Catheter Length: 220.0cm	Catheter French size: 7Fr, 10Fr Catheter Length: 220cm,	Similar dimensional specifications to the predicate device. The favorable results of the design verification and validation testing demonstrate conformance of the proposed Nexpowder™ to the FDA's recognized standards and the design requirements. The testing results further demonstrate the proposed Nexpowder™ is substantially equivalent to the predicate device, Hemospray® Endoscopic Hemostat, as the proposed Nexpowder™ and predicate device are subject to the same recognized standards of the FDA for the special controls evaluation of medical device.
Sterilization Method	Powder: Gamma radiation Delivery system (catheter and connector): EtO Sterilization Spray Body: Non-sterile	Product: Gamma radiation	Similar Gamma radiation sterilization for hemostatic agent as the predicate device
Sterilization Validation Target	Sterilization Assurance Level of 10^{-6}	Sterilization Assurance Level of 10^{-6}	Identical to the predicate devices
Shelf Life	15 months	3 Year	Supported by 15 months shelf life testing

Similar to the predicate device, Nexpowder™ is an inert powder developed for endoscopic hemostasis. Nexpowder™ contains Aldehyded Dextran and Poly-L-Lysine (Polysaccharide) derived from microbial extraction. The powder is delivered by use of a battery powered delivery system and through a catheter

inserted through the working channel of an endoscope which provides access to the intended hemostasis target site. The overall hemostatic mechanism of Nexpowder™ to form a physical control barrier to achieve hemostasis is similar to the predicate, Hemospray® Endoscopic Hemostat. The hemostatic agent of Nexpowder™ is provided in a form of powder polymer materials, which can be readily sprayed over a bleeding site in the non-variceal upper gastrointestinal tract. The hemostatic agent of powder polymer functions as a physical, mechanical barrier over the bleeding site in the gastrointestinal tract to effectively control bleeding. From the standpoint of forming the mechanical barrier physically, the presence of blood in and of itself is not required. But any type of bodily fluids including digestive fluids excreted in the gastrointestinal tract and blood at the hemostasis target site coming into contact with the Nexpowder™ would lead to the crosslinking gelation effects following the hemostatic agent's rapid absorption of the bodily fluids.

Although the hemostatic agent may differ in chemical composition for each the predicate and subject device, in both of these products, the individual ingredients do not contain human or animal proteins or botanicals and have the same end state, which is a gel that will act as a mechanical barrier and induce hemostasis. In addition, the modified polysaccharide material that comprises the hemostatic agent ingredient of the Nexpowder™ is similar to the polysaccharide material in the reference device, PerClot® Topical (K132105). PerClot® Topical is another class II, hemostat device, intended as a topical wound dressing and used to control bleeding from the skin by rapidly absorbing water and forming a gelled adhesive matrix that provides a mechanical barrier to further bleeding. This demonstrate that polysaccharides used in hemostatic agents are not novel. Moreover, the biocompatibility profile of Nexpowder™ agents has been confirmed with comprehensive biocompatibility testing pursuant to ISO 10993-1.

Utilizing a power source, both the spray body of Nexpowder™ and the predicate provide physical force to push the hemostatic powder agent into the delivery catheter and spray the hemostasis intended site in the gastrointestinal tract. The minor difference in the power source of the delivery system does not raise different questions in terms of safety and effectiveness, since Nexpowder™ delivery system has been verified to meet the electrical safety and performance requirements per the FDA's recognized standards of IEC 60601-1, IEC 60601-1-2, and IEC 60601-1-6.

VI. Biocompatibility Assessment

Nexpowder™ has met the FDA's recognized standards for biocompatibility requirements identified in the FDA Guidance Table A.1, below, Biocompatibility risk assessments have been conducted per FDA Guidance, "*Use of ISO 10993-1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing within a Risk Management Process* (Issued June 16, 2016)". The following biocompatibility testing was performed on Nexpowder™:

GLP Biocompatibility Testing Completed for the Hemostatic Agent Powder of Nexpowder™:

Biocompatibility Endpoint	Method and Purpose	Result
Cytotoxicity	ISO 10993-5: MEM Elution Study used to evaluate device extracts for cytotoxicity risks.	Non-cytotoxic
Sensitization	ISO 10993-10: Guinea Pig Maximization Sensitization Test used to evaluate device extracts for dermal sensitization risks.	Non-sensitizer

Irritation	ISO 10993-10: Intracutaneous Initiation Test used to evaluate device extracts for irritation risks.	Non-irritant
Acute Systemic Toxicity	ISO 10993-11: Acute systemic toxicity study used to evaluate device extracts for systemic toxicity risks.	No acute systemic toxicity
Material Mediated Pyrogenicity	ISO 10993-11: Rabbit pyrogen test used to evaluate device extracts for pyrogenicity risks.	Non-pyrogenic
Hemocompatibility	Hemolytic study (ASTM: F756-17), Complement Activation, Partial Thromboplastin Time, Platelet and Leukocyte Counts (ISO10993-4) used to evaluate device extracts for hemocompatibility risks.	Hemocompatible
Genotoxicity	ISO 10993-3: Genotoxicity study used to evaluate device extracts for genotoxicity risk.	Non-genotoxic
Implantation	ISO 10993-6: Implantation study used to evaluate device extracts for the local effects risk.	Non-irritant
Subchronic Toxicity	ISO 10993-11: Implantation study used to evaluate device extracts for subchronic toxicity risk.	No subchronic systemic toxicity

GLP Biocompatibility Testing Completed for the Delivery System Catheter and Connector of Nexpowder™:

Biocompatibility Endpoint	Method and Purpose	Result
Cytotoxicity	ISO 10993-5: MEM Elution Study used to evaluate device extracts for cytotoxicity risks.	Non-cytotoxic
Sensitization	ISO 10993-10: Guinea Pig Maximization Sensitization Test used to evaluate device extracts for de1mal sensitization risks.	Non-sensitizer
Irritation	ISO 10993-10: Intracutaneous Initiation Test used to evaluate device extracts for irritation risks.	Non-irritant
Acute Systemic Toxicity	ISO 10993-11: Acute systemic toxicity study used to evaluate device extracts for systemic toxicity risks.	No acute systemic toxicity
Material mediated pyrogenicity	ISO 10993-11: Rabbit pyrogen test used to evaluate device extracts for pyrogenicity risks.	Non-pyrogenic
Endotoxin	USP <85>	Non-pyrogenic
Hemocompatibility	ASTM: F756-17: Hemolytic study used to evaluate device extracts for hemocompatibility risks.	Hemocompatible

VII. Design Verification and Validation Testing

Design Verification and Validation (DV&V) testing were performed to verify that the proposed Nexpowder™ meets the pre-determined requirements for design verification, validation, and FDA's special control requirements. Testing was also conducted to verify the effectiveness of the implemented risk control measures to mitigate the risks identified within the risk management process per ISO 14971: Medical Devices-Application of Risk Management to Medical Devices. The following design verification or performance testing of Nexpowder have been completed with favorable test results, meeting the applicable ISO standards and FDA's recognized standards pertaining to evaluations of Nexpowder™.

Design Verification Performance Testing

T=0 Baseline Sample Testing, T=2 Years, and T=3 Years Accelerated Aging
Testing of Finished Hemostatic Powder Agents of Nexpowder™:

- Appearance Test
- Weight Test
- Absorption Test
- Water Content Test
- Adhesion Test

T=0 Baseline Sample Testing, T=3 Years Accelerated Aging
Testing of Catheter and Connector of Nexpowder™ Delivery System:

- Appearance Test
- Dimension Verification Test
- Tensile Strength Test
- Air Leak Test
- Spray Test

T=0 Baseline Sample Testing, T=3 Years Accelerated Aging
Testing of Spray Body of Nexpowder™ Delivery System:

- Appearance Test
- Dimension Verification Test
- Air Pressure Test of the Outlet Port
- Power Switch Function Test (Battery Function and Vibration operation Test)
- Battery Protection Film Test
- Battery Cap test
- Spray test

Design Validation Testing

- Animal Study

Test	Purpose	Method	Results
Porcine Study I	Assess hemostatic efficacy and safety of the device	**Design:** Endoscopic submucosal dissection (ESD) based bleeding models **Animals:** 6 Nexpowder™ treated, 6 Hemospray® treated, 3 sham controls **Duration:** 30-day follow-up followed by termination	Initial hemostasis was achieved in all animals (6/6). None of the animals in the treatment group showed re-bleeding up to the 30-day follow-up time point. There was no gastrointestinal perforation, obstruction, or gas embolism caused by the device. Histopathological evaluation of the device application site did not reveal any important histological differences between treatment group and control group animals.
Porcine Study II	Assess hemostatic efficacy and safety of the device	**Design:** Gastroepiploic Artery (Forrest 1a) Bleeding Model **Animals:** 6 Nexpowder™ treated, 3 Hemospray® treated **Duration:** 30-day follow-up followed by termination	The rate of achieving initial hemostasis was 67% (4/6) in the treatment group. None of the animals in the treatment group showed re-bleeding up to the 30-day follow-up time point. There were no gastrointestinal perforation, obstruction, and gas embolism which caused by device. Histopathological evaluation of the device application site did not reveal any important histological findings.

In vivo animal studies have been conducted to support the substantial equivalence claims of our product as compared to the predicate device Hemospray®. The objective of the study was to validate the efficacy and safety of Nexpowder™ (compared to the predicate device) in a porcine model for upper gastrointestinal bleeding control. The results demonstrated that the proposed is substantially equivalent to the predicate.

- Simulation System Test
- Usability Engineering Evaluation
- Clinical data

Real-world evidence of device safety in nonvariceal upper gastrointestinal bleeding in the OUS market was provided, including data from 315 patients with an additional 50 patients from a Retrospective Aggregated Data Collection survey (see table below). Hemostasis was achieved in 94-100% of patients with a re-bleed rate of <23% at 30 days.

Clinical Study Title	Number of Patients	Hemostasis (%)	Adverse Events/ Complication Rates	Re-Bleeding rate (%)	Bleeding Types of Enrolled Subjects
A. Prospective, Multicenter, Single-blind (subject) Controlled Clinical Trial to Confirm the Efficacy and Safety of the Wound Dressing 'UI-EWD'	76	100%: Test Group with Nexpowder: 37 out of 37	2.7% (1 Adverse event) out of 37 Subjects (Fever)	8.11% within 3 days	Post-ESD (86.49%, 32/37) Forrest Class Ib (75.68%, (28/37)
B. Novel hemostatic adhesive powder for nonvariceal upper gastrointestinal bleeding	56	96.4% (54 out of 56 cases with use of Nexpowder)	Zero adverse events	3.7% Within 30 days	Post-procedure (97.80%, 45/56) Forrest Class Ib (97.20%, (28/)
C. Efficacy of a novel hemostatic adhesive powder in patients with refractory upper gastrointestinal bleeding: a pilot study	17	94% (16 out of 17 cases with use of Nexpowder)	Zero adverse events	19% Within 30 days	Refractory bleeding Forrest Ia (11.8%, 2/17) Forrest Ib (88.2%, 15/17)
D. Efficacy of a novel hemostatic adhesive powder in patients with upper gastrointestinal tumor bleeding	41	97.5% (40 out of 41 cases with use of Nexpowder)	Zero adverse events	4.3% within 7 days 22.5% within 28 days	Forrest Ib (100.0%)
E. Post Market Clinical Aggregated Data Collection Survey on Nexpowder™ for Safety and Performance Evaluation	50	100% (50 out of 50 cases with use of Nexpowder)	Zero adverse events	2.0% within 3 days 4.0% within 30 days	Peptic ulcer (24%, 12/50) Tumor bleed (8.0%, 4/50) Prevent delayed bleeding (30%, 15/50)

VIII. Sterilization Validation and Verification

The following sterilization and verification testing was performed:

- Gamma Sterilization Validation Testing of Hemostatic Powder Agent
- EtO Sterilization Validation Testing of Delivery Catheter/Connector
- Sterility Test of Nexpowder, Catheter and Connector both with the baseline time-zero samples and three-year aged samples

IX. Packaging Validation, Verification and Distribution Test

The following packaging validation, verification and distribution testing was performed:

- Packaging Validation Testing of Hemostatic Powder Agent
- Package Seal Peeling Test and Dye Penetration Test of Nexpowder™ Catheter and Connector both with the baseline time-zero samples and three-year aged samples
- Package Seal Peeling Test and Dye Penetration Test of Nexpowder™ Spray Body both with the baseline time-zero samples and three-year aged samples

- Distribution Transportation Test of Nexpowder™

X. Conclusion

Nexpowder™ functions as intended, and is substantially equivalent to the predicate, Hemospray® Endoscopic Hemostat (DEN170015). Nexpowder™ has the similar intended use and indications for use, and similar key technological and design characteristics and mechanism of action compared to the predicate device. The minor differences between the subject and predicate devices do not raise different questions of safety or effectiveness as the design verification and performance testing data support that the Nexpowder™ is substantially equivalent to the predicate device.