February 4, 2025

Geon Corporation
Henry Chen
General Manager
No. 12, Gung Ye Road
Hsi Hu
Chang Hwa Hsien, 514
Taiwan

Re: K243138
Trade/Device Name: Geon (S2) Nasal Aspirator
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: January 8, 2025
Received: January 8, 2025

Dear Henry Chen:

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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.

Submission Number *(if known)*

K243138

Device Name

Geon (S2) Nasal Aspirator

Indications for Use *(Describe)*

Geon (S2) Nasal Aspirator is a hand-held, non-invasive, electronic medical device that provides negative pressure to remove nasal secretions and mucus from children (age 2-12 years old) at home environment.

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.

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510(k) #: K243138

510(k) Summary

Prepared on: 2025-01-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Geon Corporation
Applicant Address	No. 12, Gung Ye Road, Hsi Hu, Chang Hwa Hsien 514 Taiwan
Applicant Contact Telephone	(886)48852476
Applicant Contact	Mr. Henry Chen
Applicant Contact Email	info@geon.com.tw

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Geon (S2) Nasal Aspirator
Common Name	Powered suction pump
Classification Name	Pump, Portable, Aspiration (Manual Or Powered)
Regulation Number	878.4780
Product Code(s)	BTA

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220126	Geonic	BTA

Device Description Summary

21 CFR 807.92(a)(4)

Geon Nasal Aspirator, model S2, is a hand-held, non-invasive, electronic medical device that provides negative pressure to remove nasal secretions and mucus from children (age 2-12 years old). Geon (S2) Nasal Aspirator is intended for over-the-counter (OTC) use at home environment.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Geon (S2) Nasal Aspirator is a hand-held, non-invasive, electronic medical device that provides negative pressure to remove nasal secretions and mucus from children (age 2-12 years old) at home environment.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indication of use the subject devices (Model S2) is same as the predicate device K220126.

Technological Comparison

21 CFR 807.92(a)(6)

The Geon Nasal Aspirator (Model Name: S2) is substantially equivalent the predicates Geonic Nasal Aspirator (K220126) as a CFR 880.4780 Powered Suction Pump. The subject device and predicates (K220126) have the same Indication for use, Motor type (3V DC), and Type BF applied part, Contact parts and materials. The main principle of operation is to utilize a pump to generate negative pressure in the suction system, which allows nasal secretions to flow into the device container. All of these are a portable, DC powered devices intended to provide the suction function to aspirate children's nasal secretion from the same population of children (age 2-12 years old). The subject device has similar characteristics as the predicates (K220126), including Vacuum pressure, Storage container size, Noise level,

Suction Tip, Power source, Materials, Operating condition and Storage condition. The main difference between the subject device and the predicates (K220126) is the shape of the suction tip. It does not impact the safety and effectiveness.

The difference in design does not affect performance, or raise different questions of safety and effectiveness. The direct and indirect tissue contacting materials of the subject device are same as the predicates (K220126), thus the subject device also meets the requirement of biocompatibility. The subject device complies with general requirements for basic safety and essential performance, and electromagnetic compatibility according to IEC 60601-1, IEC60601-1-2, and IEC 60601-1-11.

By definition, the subject device, (Geon (S2) Nasal Aspirator is substantially equivalent to the predicate device, K220126. Bench testing contained in the submission demonstrates the device does not raise different questions regarding its safety and effectiveness as compared to the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The evaluation of suction vacuum and noise were completed during verification testing of Geon (S2) Nasal Aspirator. The test reports showed that the device passed all the testing. For Model S2, no individual differences exceed the specified limits of the respective tolerance of suction vacuum and noise after the cleaning and disinfection procedure. As part of demonstrating the acceptable performance of the Geon (S2) Nasal Aspirator in showing substantial equivalence to the predicate device:

1. Suction vacuum
   54kPa ~ 66kPa (tolerance: 3 kPa)
   K220126: 52-64 Kpa (claimed), 57~60 Kpa (Head-to-head test)
2. Noise
   55dB~ 60dB (tolerance: 5 dB)
   K220126: 55dB~60dB (claimed), 57~60dB (Head-to-head test)

The device meets all the requirements for the specifications defined by the manufacturer.