April 10, 2024

Surnic Corporation
Helen Xie
Project Director
480 Apollo Street, Ste. D
Brea, California 92821

Re: K233789
Trade/Device Name: 8Q10 Surclear Smoke Plume Evacuation System
Regulation Number: 21 CFR 878.5070
Regulation Name: Air-handling apparatus for a surgical operating room
Regulatory Class: Class II
Product Code: FYD
Dated: March 11, 2024
Received: March 11, 2024

Dear Helen Xie:

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.

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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2024.04.10 10:49:42 -04'00'

For:

Christopher Dugard
Assistant Director
DHT4B: Division of Infection Control
and 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)*
K233789

Device Name
8Q10 Surclear Smoke Plume Evacuation System

Indications for Use *(Describe)*
The Surnic Surclear Smoke Plume Evacuation System with accessories is intended to remove smoke created in surgical procedures at the surgical site.

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 – K233789

Company Surnic Corporation
480 Apollo Street Ste. D
Brea, CA 92821 USA

Contact Helen Xie
Telephone: (909) 979-9801
Email: helen@surnic.com

1.0 Date Prepared

April 1, 2024

2.0 Device Name

Trade Name: 8Q10 Surclear Smoke Plume Evacuation System

Model: 8Q10

Common Name: Smoke Evacuator

3.0 Classification Name

Air-handling apparatus for surgical operating room (21 CFR 878.5070, Product Code FYD)

Regulatory Class

Class II

4.0 Predicate Device

The predicate device (K131402) is Visiclear Smoke Evacuation System by Buffalo Filter Co, Inc.

5.0 Device Description

The Surclear 8Q10 have been designed with a high suction, high flow rate vacuum motor. The ultra-quiet motor is used to draw the surgical smoke from the surgical site through the vacuum tubing and into the Surclear 8Q10 filter 8QF1 where the surgical smoke is processed by a series of filters. A single disposable filter is used to simplify the installation and removal during filter changes. The filter is completely enclosed to protect the healthcare personnel from potential contamination during filter changes. One 8QF1 filter contains four different stages within to capture the smoke plume.

6.0 Indications for Use

The Surnic Surclear smoke plume evacuation system with accessories is intended to remove smoke created in surgical procedures at the surgical site.

7.0 Technological Characteristics

Device	K233789	K131402	Discussion
	Subject	Predicate	
Indications for Use	The Surnic Surclear Smoke Plume Evacuation System with accessories is intended to remove smoke created in surgical procedures at the surgical site.	The visiclear smoke evacuation system is designed to remove and filter smoke and aerosols from a surgical site produced during electrosurgical and laser procedures	Similar
Static Motor Suction	25.69 kPa	25.69 kPa	Same
Flow rates (Max)	25 cfm (707lpm) @7/8(22mm) tubing	30 cfm (839lpm) @7/8(22mm) tubing	Similar, (cfm) 25vs30 is due to different manufacturers' understanding of the maximum flow limit required in actual applications.
Suction control level	10 Level	10 Level	There are 10 control levels of suction rate from 10% to 100%.
Suction blockage warning	Yes	Yes	An occlusion warning safety feature alerts the operator when an occlusion has occurred.
Foot control	Yes	Yes	The operator can foot-control the suction of the device to turn on or off.
Filter life indication	Yes	Yes	Counter indicates filter status and lifetime.

Filter performance	The filter is 99.99% efficiency at 0.1-to-0.2-micron particle size with a filter life of up to 40 hours.	The filter is 99.99% efficiency at 0.1-to-0.2-micron particle size with a filter life of up to 35 hours.	Same filter efficiency, larger filters can increase application time from 35 to 40 hrs.
Power Supply	100-120VAC, 50/60Hz 9A max 220-240VAC, 50/60Hz 4.5A max	100/240VAC, 50/60Hz 220/240 VAC	Same

8.0 Non-clinical Tests

Non-clinical testing was conducted to demonstrate that the Surclear Smoke Plume Evacuation System with its accessories functions as intended. Below is a summary of testing conducted on the subject device:

Title of Test	Purpose of Test	Acceptance Criteria	Results
Electrical Safety Testing	Evaluate Electrical Safety	Fulfil the requirement of IEC 60601-1:2012+2020 as applicable	Passed
Electromagnetic Compatibility	Evaluate Electromagnetic Compatibility	Fulfil the requirements of IEC 60601-1-2:2014+2020 as applicable	Passed
Software Validation	Evaluate Device Software	All test cases shall pass or deviations explained as to why it is acceptable	Passed
Flow Rate Testing	Evaluate flow rate against design requirement	The flow rates at each flow mode are within the defined tolerances.	Passed
Plume Evacuation Evaluate	Evaluate System for evacuation of plume generated by medical devices	Fulfil the requirements of ISO 16571:2014 as applicable	Passed

9.0 Conclusions

The conclusions drawn from the non-clinical testing of Surclear Smoke Plume Evacuation System demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device (K131402).