March 15, 2024

Starch Medical, Inc.
Alice Li
Regulatory Affairs Project Manager
2150 Ringwood Ave.
San Jose, California 95131

Re: K240454
Trade/Device Name: RESPONDER® Polysaccharide Hemostat
Regulatory Class: Unclassified
Product Code: QSY
Dated: February 15, 2024
Received: February 15, 2024

Dear Alice Li:

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
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)*
K240454

Device Name
RESPONDER® Polysaccharide Hemostat

Indications for Use *(Describe)*
RESPONDER® Polysaccharide Hemostat OTC is indicated for the local management of bleeding such as lacerations, minor cuts and abrasions.

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) Summary

[As required by 21 CFR 807.92]

1. Submitter's Information

Name of Sponsor:	Starch Medical Inc.
Address:	2150 Ringwood Avenue San Jose California USA
Contact Name:	Alice Li
Telephone No.:	408-428-9818
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Email Address:	alice@starchmedical.com

2. Correspondent's Information

Company Name:	Starch Medical Inc.
Correspondent Name:	Alice Li
Telephone No.:	408-428-9818
Email Address:	alice@starchmedical.com

3. Trade Name, Common Name, Classification

Trade Name:	RESPONDER®
Device Name:	Responder® Polysaccharide Hemostat
Mode Name:	RP0002/RP0003/RP0005
Regulation Classification	Unclassified
Product Code:	QSY
Classification Panel:	General and Plastic Surgery
Device Class:	

4. Identification of Predicate Device(s)

The identified predicates within this submission are as follows:

Responder® Polysaccharide Hemostat has been cleared by FDA through K220525 (Decision Date- December 04, 2023)

5. Description of the Device

Responder® Polysaccharide Hemostat has been cleared by FDA through K220525 (Decision Date- December 04, 2023) for both Rx and OTC indications. This submission is intended to add three models containing smaller hemostatic powder of 2g, 3g and 5g to the OTC indications. There are no changes on raw material, production technique, packaging, sterilization, and indications for these three new models comparing with cleared products.

RESPONDER® Polysaccharide Hemostat (RESPONDER®) is a medical device composed of absorbable modified polymer (AMP®) particles. AMP® particles are biocompatible, non-pyrogenic and derived from plant starch. The device contains no human or animal components.

6. Intended Use/Indication for Use

RESPONDER® Polysaccharide Hemostat OTC is indicated for the local management of bleeding such as minor lacerations, minor cuts and minor abrasions.

7. Technological Characteristics

The three new models RP0002, RP0003 and RP0005 are identical with RESPONDER® Polysaccharide Hemostat (K220525) in aspects of composition, form of device, method of application, sterilization, mechanism of action, biocompatibility, and resorption performance. The intended use is identical with the OTC indications of RESPONDER® Polysaccharide Hemostat (K220525) as well.
It is concluded that the subject device is substantially equivalent with the predicate device RESPONDER® Polysaccharide Hemostat (K220525) in OTC indications.

8. Performance

The subject device has the same physical structure (Granules), same packaging (Foil Pouch) and same shelf life as that of the predicate. Both of the devices can achieve hemostasis by forming a gel barrier. The bio-compatibility, sterility and performance of the subject device have been verified in the submission of RESPONDER® Polysaccharide Hemostat (K220525).It is concluded that the proposed device is as safe as the predicate device.

9. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Starch Medical Inc. concludes that RESPONDER® Polysaccharide Hemostat is substantially equivalent to predicate devices with regard to safety and performance.