April 19, 2024

Incore Co., Ltd.
% Milly An
Consultant
KMC, Inc.
Room no. 1709, 123, Digital-ro 26-gil, Guro-gu
Seoul, 08390
Korea, South

Re: K232216
Trade/Device Name: Hemoblock_S (Prescription); Hemoblock_S (OTC)
Regulatory Class: Unclassified
Product Code: QSY
Dated: March 18, 2024
Received: March 19, 2024

Dear Milly An:

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,

Mustafa A. Mazher -S

for 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

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)*
K232216

Device Name
Hemoblock_S (Prescription);
Hemoblock_S (OTC)

Indications for Use *(Describe)*
Hemoblock_S (Prescription): For use as a temporary external dressing to control moderate to severe bleeding and manage external abrasions and lacerations

Hemoblock_S (OTC): To control bleeding of minor lacerations, minor cuts and minor 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

1. INFORMATION

1.1 Submitter Information

- Submitter Name: INCORE Co., Ltd.
- Address
  : 11, Hyeoksin-daero 78-gil, Dong-gu, Daegu, Republic of Korea
- Telephone Number: +82-2-866-3514
- Fax: +82-2-6919-1346

1.2 Official Correspondent Person

- Name: Milly (Consultant / KMC, Inc.)
- Address: Rm. No. 1709, 123, Digital-ro 26-gil, Guro-gu, 08390, Republic of Korea
- Telephone Number: +82-70-8965-5554
- Fax: +82-2-2672-0579
- E-mail: milly@kmcerti.com

1.3 Date prepared: April 16, 2024

2. DEVICE INFORMATION

2.1 Trade Name / Proprietary Name: Hemoblock_S (Prescription), Hemoblock_S (OTC)

2.2 Common Name: Non-absorbable Hemostatic Dressing

2.3 Product Code: QSY

2.4 Device Class: Unclassified

2.5 Panel: General & Plastic Surgery

3. PREDICATE DEVICE

Manufacturer	SAM Medical Products
Device Name (Trade Name)	Chito-SAM TM 100(Prescription use) Chito-SAM TM Active (Over-the-counter Use)
510(k) Number	K133121

4. Device Description

The Hemoblock_S (Hemoblock_S (Prescription Use) and Hemoblock_S (OTC Use)) for being placed on the U.S.A Market is single use, hemostatic dressing made of Chitosan and Cotton. This device is called to Hemoblock Gauze on the Republic of Korea Market.

Chitosan is a naturally occurring polysaccharide usually derived from shellfish, and its hemostatic properties are widely recognized in the biomedical field. When applied directly on a wound with firm pressure, the Hemoblock_S acts as a mechanical barrier against bleeding by turning into a gel-like

condition to absorb the blood and assist in temporarily controlling moderate to severe bleeding. The Hemoblock_S is provided in two different types to accommodate a variety of treatment regions, according to being based on the whether strap yan which is consisted with Nylon and handle for remove a device into any wound, with following;

- Gauze(N) Type: There is not strap yarn part on the Hemoblock_S
- Gauze(S) Type: There is strap yarn part on the Hemoblock_S

The Hemoblock_S is individually packaged in a foil pouch and is Irradiation sterilized in accordance with ISO 11137 Series.

Hemoblock_S is provided in different size for each types as listed below.

Type	Thickness (Unit: mm)	Wide x Length (Unit: cm)	Stran yan length (Unit: cm)
Gauze(N) Type	0.4	7.5 x 10, 7.5 x 20	N/A
		7.5 x 100, 7.5 x 200, 7.5 x 300, 7.5 x 370	
		5.0 x 5.0, 5.0 x 7.5, 5.0 x 40	
		3.5 x 20	
		12 x 300	
		10 x 10	
Gauze(S) Type	1.5	9 x 36	18
		18 x 36	

5. INDICATIONS FOR USE

Hemoblock_S (Prescription): For use as a temporary external dressing to control moderate to severe bleeding and manage external abrasions and lacerations

Hemoblock_S (OTC): To control bleeding of minor lacerations, minor cuts and minor abrasions.

6. SUBSTANTIAL EQUIVALENCE

Descriptive Information	Subject Device		Predicate Device		Comparison
Manufacturer	INCORE, Co., Ltd.		SAM Medical Products		N/A
Product Name	Hemoblock_S		Chito-SAM		N/A
	Hemoblock_S (Prescription Use)	Hemoblock_S (OTC Use)	Chito-SAM 100 (Prescription Use)	Chito-SAM Active (OTC Use)	
510(K) Number	K232216		K133121		N/A
Product Code	QSY		QSY		Identical
Indications for Use	For use as a temporary external dressing to control moderate to severe bleeding and manage external abrasions and lacerations.	To control bleeding of minor lacerations, minor cuts and minor abrasions	For use as a temporary external dressing to control moderate to severe bleeding and manage external abrasions and lacerations.	To control bleeding of lacerations, minor cuts and abrasions	Identical
Anatomical Site	External Wounds		External Wounds		Identical
Material	Gauze: Chitosan (derived from shellfish) Bleached cotton Polypropylene Barium sulfate Nylon-6		Gauze: Chitosan (derived from shellfish)		Different (Only gauze part is same)
Physical Form	Sheet Form		Sheet Form		Identical
Size (W x L)	7.5cm x 10cm 7.5cm x 20cm 7.5cm x 100cm 7.5cm x 200cm 7.5cm x 300cm 7.5cm x 370cm 5.0cm x 5.0cm 5.0cm x 7.5cm 5.0cm x 40cm 3.5cm x 20cm 12cm x 300cm 10cm x 10cm	7.5cm x 10cm 7.5cm x 20cm 7.5cm x 100cm 7.5cm x 200cm 7.5cm x 300cm 7.5cm x 370cm 5.0cm x 5.0cm 5.0cm x 7.5cm 5.0cm x 40cm 3.5cm x 20cm 12cm x 300cm 10cm x 10cm	10cm x 10cm 7.6cm x 122cm 7.6cm x 183cm	7.5cm x 180cm 10cm x10cm	Different

	9cm x 36cm 18cm x 36cm	9cm x 36cm 18cm x 36cm			
Sterilization	Irradiation (E-beam)		Irradiation (Gamma)		Different
Single Use/Re-use	Single Use		Single Use		Identical
Shelf Life	5 years		3 years		Different
Packaging	Foil Bag		Foil Bag		Identical

The indications for use for the predicate devices is substantially equivalent to the proposed indications for use for the Hemoblock_S. The technological characteristics of the Hemoblock_S are similar to the predicate devices. Available data, including biocompatibility test, sterilized validation and performance data, support the determination of substantial equivalence. Minor differences, such as size, sterilization method and shelf life, between both devices do not raise any new issues of safety or effectiveness. Thus, the Hemoblock_S is substantially equivalent to the predicate devices

7. Non-Clinical Testing

7.1 Biocompatibility Test

Biocompatibility Testing per ISO 10993-1 and FDA guidance ("Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process") was performed for:

Nature of body contact		**Contact Duration**	**Biological Effects -Test Items**
Category	**Contact**		
Surface devices	Breached or compromised surface	A- limited (≤ 24h)	Cytotoxicity Test
			Sensitization
			Irritation or intracutaneous reactivity
			Material mediated pyrogenicity
			Acute systemic toxicity

7.2 Sterilization and Shelf life

Hemoblock_S is supplied sterile in a foil bag. It is sterilized using Irradiation (E-beam) to a sterility assurance level (SAL) of 10-6 . E-beam sterilization validation was performed in compliance with the ISO 11137-1 and ISO 11137-2 and ISO 11137-3 standards.

Following the E-beam sterilization, the packaging was subjected to sterile barrier testing to validate a shelf life of three (5) years as per ISO and ASTM standards.

- The stability and effectiveness of packaging of the sterilized product during the shelf-life period was confirmed by real time stability studies and accelerated aging test, per ASTM F-1980
- Package seal strength per ASTM F88/F88M
- Dye migration test as per ASTM F1929
- Sterility test as per ISO 11737-2.

7.3 Performance Test – Non clinical

The physical performance test results all meet the requirements of the acceptance criteria

- Physical Test
  - Appearance
  - Dimension
  - Tensile Strength (ISO 9073-18)
  - Absorption (EN 13726-1)
  - Nylon Tensile Strength (ASTM D2256)
  - X-ray impermeableness
- Virus Inactivation Validation Report
- In Vitro Blood Clotting Test

7.4 Performance Test – Animal Test

In the animal study conducted, 12 females New Zealand white rabbit were randomly assigned for in vivo hemostatic testing.

8. Conclusion

The Hemoblock_S is substantially equivalent to the predicate device in terms of materials, technological characteristics, indications for use, and performance. No new issues of safety or effectiveness are raised by the Hemoblock_S.