December 15, 2021

Human Biosciences, Inc.
% Jack Slovick
VP Quality & Regulatory
Methodize
P.O. Box 463
Nevis, Minnesota 56467

Re: K213092
Trade/Device Name: Cellusheet, Cellufil
Regulatory Class: Unclassified
Product Code: KGN
Dated: July 30, 2021
Received: September 24, 2021

Dear Jack Slovick:

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,

Julie Morabito, Ph.D.
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)*
K213092

Device Name
Cellusheet Dressing and Cellufil Particles

Indications for Use *(Describe)*
The device is intended for the management of minor cuts, minor scrapes, minor bruises, minor abrasions, minor lacerations, and minor burns.

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 21CFR 807.92 (c)]

510k #: K213092
Date Summary Prepared: July 30, 2021
Submitter Information
Name of Manufacturer/Owner of 510(k): Human Biosciences Inc
Address: 940 Clopper Rd, Gaithersburg, MD 20878
FDA Establishment Registration Number: 3008770963
Contact Person: Primary Contact: Jack Slovick (Vice President of Quality & Regulatory)
Secondary Contact: Jigar Patel (Operations Manager)

Email Address: Jack Slovick: jlslovick@gmail.com
Phone Number: +1 – 301 – 740 – 1893
Fax Number: +1 – 301 – 740 - 1899
Name Change

A name change is proposed to the Device Name/Trade Name for both the products part of this submission. For OTC variants of the products, the following names are proposed:

Serial Number	Device Identification in the Submission	510(k) Number	Prescription Use (Rx) Name	Over-The-Counter (OTC) Name
1	Device 1	K122325 K925545 K913023	SkinTemp II Dressing	Cellusheet Dressing
2	Device 2	K925545 K910944	Medifil II Particles	Cellufil Particles

Submission Type and Product Information

Type of 510(k) submission: Special

Device 1
Subject: Name of Device/Trade Name (OTC): Cellusheet Dressing
Predicate: Name of Device/Trade Name (Rx): SkinTemp II Dressing (K122325)

Device 2
Subject: Name of Device/Trade Name (OTC): Cellufil Particles
Predicate: Name of Device/Trade Name (Rx): Medifil II Particles (K910944 & K925545)

Additional Reference Device:
Name of Device/Trade Name (OTC): Hydrolyzed Collagen with 10% Chondroitin Sulfate Wound Gel (K081724)

Product Classification Details:

- Device: Dressing, Wound, Collagen
- Product Code: KGN
- Device Class: Unclassified
- Unclassified Reason: Pre-Amendment Device
- Premarket Review: Infection Control and Plastic Surgery Devices (DHT4B)

Device Information

DEVICE 1 – CELLUSHEET DRESSING

Description

Cellusheet Dressing is a soft, sterile, flexible, disposable, absorbent & conformable single use wound dressing. It is hydrophilic dressing composed of fibrous bovine collagen and a non-adherent backing layer. The dressing absorbs wound drainage to cover the topical wounds to provide moist wound environment. The Cellusheet Dressing will be available in 2"X2", 3"X4" and 8"X12" sizes.

Cellusheet Dressing is made up of collagen which is the most abundant protein in the human body and to cover the topical wounds to provide moist wound environment.
The dressing will be packaged in a single use Tyvek pouch (1059B). Each Tyvek Pouch will contain one dressing sheet. 5 Tyvek pouches will be packaged in a box. Sterility is guaranteed for unopened and undamaged packaging.

The bovine collagen used in this device is derived from cowhides that are sourced from certified negligible Bovine Spongiform Encephalopathy (BSE) risk region designated by the World Organization for Animal Health [formerly the OIE (Office International des Epizooties)].

Product List

HBS Reorder Number	Size	Moisture Content	Shelf Life
CS5000	2"X2"	< 17%	5 Years
CS5001	3"X4"	< 17%	5 Years
CS5002	8"X12"	< 17%	5 Years

Device Constituents

- Bovine Collagen
- Demineralized Water
- Buffering agent (HBS Proprietary Name "Chemical Z")

Device 1 Illustrations

Figure 0-1: Cellusheet Dressing

Figure 0-2: Non-adherent backing of Cellusheet Dressing

DEVICE 2 – CELLUFIL PARTICLES

Description

Cellufil Particles is a bovine (cattle) collagen wound dressing that is sterile, off-white powder that absorbs wound drainages. The dressing is an off-white, colored powder made up of collagen cover the topical wounds to provide moist wound environment. Cellufil Particles consists of spherical hydrophilic particles 0.1mm to 0.3mm in diameter.

The particles will be packaged in single use Tyvek pouch (1059B). Each Tyvek Pouch will contain one gram of the powder. 5 Tyvek pouches will be packaged in a box.

The bovine collagen used to make this device is derived from cowhides that are sourced from certified negligible Bovine Spongiform Encephalopathy (BSE) risk region designated by the World Organization for Animal Health [formerly the OIE (Office International des Epizooties)].

Product List

HBS Reorder Number	Size and Packaging	Moisture Content	Shelf Life
CF6000	1 gm in Pouch	< 17%	5 Years

Device Constituents

- Bovine Collagen
- Buffering agent (HBS Proprietary Name “Chemical Z”)

Device 2 Illustration

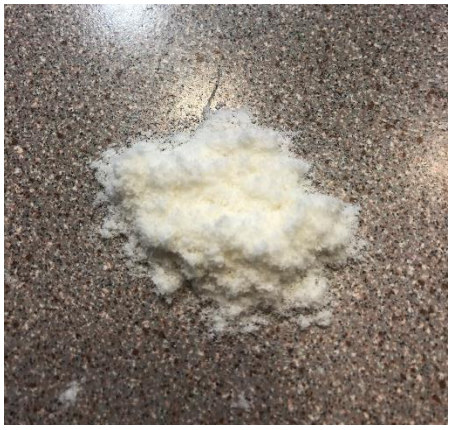

Figure 3: Cellufil Particles

Indications for Use (for Device 1 and 2):

Intended for management of minor cuts, minor scrapes, minor bruises, minor abrasions, minor lacerations, and minor burns.

Summary of Technological Characteristics

The Cellusheet Dressing and Cellufil Particles are comparable in technological characteristics to the predicate devices: Human Biosciences Inc SkinTemp II Dressing and Medifil II Particles respectively per 21 CFR Part 807.92(a)(5). The following tables show where the subject devices are similar to and different from the predicate devices in terms of technological characteristics.

DEVICE 1 (CELLUSHEET DRESING) - SUBSTANTIAL EQUIVALENCE SUMMARY

- Predicate Device: SkinTemp II Dressing
- 510(k) Number: K122325
- Name of Manufacturer: Human Biosciences Inc

Table 1-1: Substantial equivalence comparison between predicate device and submission device

Detail	Predicate Device SkinTemp II Dressing	Submission Subject Device Cellusheet Dressing	Comparison
510(k) Number	K122325	K213092	N/A
Intended Use	Management of wounds	Management of wounds	Same
Indications for Use	The device is intended for the management of burns, sores, blisters, scrapes, ulcers and other wounds.	Intended for management of minor cuts, minor scrapes, minor bruises, minor abrasions, minor lacerations, and minor burns.	Different
Sterilization	E-beam. Product supplied STERILE	E-beam. Product supplied STERILE	Same

Storage Conditions	Store in a cool and dry place	Store in a cool and dry place	Same
Design	Soft, sterile, disposable, absorbent & conformable single use wound dressing with non-adherent backing.	Soft, sterile, disposable, absorbent & conformable single use wound dressing with non-adherent backing.	Same
Primary Constituent	Bovine Collagen	Bovine Collagen	Same
Materials	Bovine Collagen Demineralized Water Buffering agent / Chemical Z (proprietary name)	Bovine Collagen Demineralized Water Buffering agent / Chemical Z (proprietary name)	Same
Usage Type	Single Patient Use	Single Patient Use	Same
Shelf Life	5 years	5 years	Same
Configurations	2"X2", 3"X4" and 8"X12"	2"X2", 3"X4" and 8"X12"	Same
Packaging	5 sheets per box	5 sheets per box	Same
Rx vs. OTC	Rx	OTC	Different
Device Class and Product Code	Unclassified, KGN	Unclassified, KGN	Same
Biocompatibility	All testing was performed as per FDA biocompatibility guidance on ISO 10993	All testing performed on predicate will be applicable since there is no change in the product specifications.	Same

DEVICE 2 (CELLUFIL PARTICLES) - SUBSTANTIAL EQUIVALENCE SUMMARY

- Predicate Device: Medifil II Particles
- 510(k) Number: K910944 & K925545
- Name of Manufacturer: Biocore Medical Technologies/Human Biosciences Inc
- Substantial Equivalence Comparison

Table 1-2: Substantial equivalence comparison between predicate device and submission device

Detail	Predicate Device Medifil II Particles	Submission Subject Device Cellufil Particles	Comparison
510(k) Number	K910944 & K925545	K213092	N/A
Intended Use	Management of wounds	Management of wounds	Same
Indications for Use	The device is intended for the management of burns, sores, blisters, scrapes, ulcers and other wounds.	Intended for management of minor cuts, minor scrapes, minor bruises, minor abrasions, minor lacerations, and minor burns.	Different
Sterilization	E-beam. Product supplied STERILE	E-beam. Product supplied STERILE	Same
Storage Conditions	Store in a cool and dry place	Store in a cool and dry place	Same
Design	Medifil II Particles is a bovine (cattle) collagen wound dressing that is sterile.	Cellufil Particles is a bovine (cattle) collagen wound dressing that is sterile.	Same

Primary Constituent	Bovine Collagen	Bovine Collagen	Same
Materials	Bovine Collagen Buffering agent / Chemical Z (proprietary name)	Bovine Collagen Buffering agent / Chemical Z (proprietary name)	Same
Particle Size	0.1mm – 0.3mm	0.1mm – 0.3mm	Same
Usage Type	Single Patient Use	Single Patient Use	Same
Shelf Life	5 years	5 years	Same
Configuration	1gram powder in one pouch	1gram powder in one pouch	Same
Packaging	5 powder pouches per box	5 powder pouches per box	Same
Rx v/s OTC	Rx	OTC	Different
Device Class and Product Code	Unclassified, KGN	Unclassified, KGN	Same
Biocompatibility	All testing was performed as per FDA biocompatibility guidance on ISO 10993.	All testing performed on predicate will be applicable since there is no change in the product specifications.	Same

Reference Device (K081724) Description - Hydrolyzed Collagen with 10% Chondroitin Sulfate Wound Gel

Hydrolyzed Collagen with 10% Chondroitin Sulfate (PSGAG, Polysulfated glycosaminoglycan) Wound Gel is a line extension of the previously cleared HyCure® Hydrolyzed Collagen (K955506). Hydrolyzed Collagen with 10% Chondroitin Sulfate (PSGAG, Polysulfated glycosaminoglycan) contains Chondroitin Sulfate as Chondroprotec® previously cleared for market via 510(k) (K961930). Hydrolyzed Collagen with 10% Chondroitin Sulfate Wound Gel contains a high concentration of water bound to the hydrolyzed collagen which maintains a moist wound environment as it manages wound healing. Hydrolyzed Collagen with 10% Chondroitin Sulfate (PSGAG, Polysulfated glycosaminoglycan).

Device Changes From Predicates

The intent of this special 510(k) is to modify the previously cleared SkinTemp II Dressing (K122325) and Medifil II Particles (K910944, K925545) manufactured by Human Biosciences Inc to include Over-the-counter use. The devices subject of this submission are the same devices as the cleared devices under 510(k) number K122325 and K910944/K925545, respectively.

Difference in Indications for Use

The subject devices and the predicate devices share the same intended use. The difference in indications from prescription to OTC do not raise different questions of safety or effectiveness. The use of these products for minor wounds is intuitive. Similar products already exist in the OTC market (see K081724).

Summary of Non-Clinical Testing

The subject devices are the same as the predicate devices in all technological characteristics, geometric specifications, packaging, sterilization, manufacturing process and raw materials used. The subject devices do not raise any different questions of safety and effectiveness with regards to the technological characteristics. The biocompatibility testing performed on the predicate devices

will be applicable to the subject devices since there is no change to the technological characteristics of the device. Additionally, the product integrity testing over the shelf-life period will also be applicable to the subject device in this case. All the testing was submitted in K122325 for SkinTemp II Dressings i.e., the predicate for Device 1 and K910944 for Medifil II Particles i.e., the predicate for Device 2. The only difference between the subject devices and the predicate devices is an Over-The-Counter indication for use compared to Prescription Use Only for the predicate devices.

Conclusion

The Cellusheet Dressing (Device 1) and Cellufil Particles (Device 2) are substantially equivalent to the respective predicate devices, SkinTemp II Dressing (K122325) and Medifil II Particles (K910944, K925545), with OTC support from the K081724 predicate:

1. Both the devices have same intended use.

2. All the devices have similar technological characteristics in terms of primary constituent, raw material used, sterilization method, geometric specifications and design of the device.

Biocompatibility tests, stability test, and sterilization validation performed on the predicate devices are applicable to the current devices and hence raise no new questions on safety and effectiveness are raised.

Hence, a determination of substantial equivalence is supported.