DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 23, 2017

BU Polysciences Equipment & Trading, LLC
N. Umamaheswaran
President
10855 Symphony Park Dr.
North Bethesda, Maryland 20852

Re: K153138
Trade/Device Name: Cerdak Basic
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 16, 2017
Received: May 19, 2017

Dear N. Umamaheswaran:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No 0910-0120
Expiration Date: January 31 2017

See PRA Statement Below

Indications for use

510(K) Number *(if known)*
K153138

Device Name

CERDAK™

Indications for Use *(Describe)*

For the management of the following:

Minor Cuts

Minor Abrasions

Minor Lacerations

Minor Burns (1st degree 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.

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510(k) summary as described in § 807.92

Submitter: **BU Polysciences Equipments & Trading, LLC**
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301 325 5574 (Mobile)

Contact Person: **N. T. Umamaheswaran (Uma) President**,
BU Polysciences Equipments & Trading, LLC
Phone: 301 325 5574 (Mobile)
bupet2015@gmail.com

Manufacturer: **CARBORUNDUM UNIVERSAL LIMITED**
655 T.H.ROAD
THIRUVOTTIYUR
CHENNAI 600019 INDIA

Preparation Date: June 19, 2017

Proprietary Device name: **CERDAK™ (K153138)**

Common Name : DRESSING

Device Classification:

Product Code : FRO (Dressing)

Regulatory Class : Unclassified

Predicate Device **:** WoundStat Wound Dressing (K071936)

Description:

Cerdak™ is a single-use, sterile, bio-compatible device made of Aluminum Oxide ceramic granules in a non-woven fabric sachet.

Cerdak™ dressing is provided in four configurations, they are: Basic, Aerofilm, Aerocloth and Drydoc and in several sizes ranging from 15mm X 25mm to 100mm X 250 mm.

CERDAK™ covers and provides moist wound environment.

It is contra-indicated for dry wounds.

Indications for use:

For the management of the following:

Minor Cuts
Minor Abrasions
Minor Lacerations
Minor Burns (1st degree burns)

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The purpose of this 510(k) is to obtain clearance to market CERDAK™ as a wound dressing. CERDAK™ is substantially equivalent to the predicate device with respect to design and intended use.

We have chosen WoundStat Wound Dressing (K071936) as our primary predicate device.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

CERDAK™ is a non-woven fabric sachet filled with micro-porous ceramic granules that covers and provides moist wound environment

CERDAK™ is similar to WoundStat Wound Dressing (K071936) which is a clay based, granular haemostatic agent. WoundStat is offered in a moisture-impermeable, sterile, 5.5-ounze foil pouch.

STATEMENT OF SUBSTANTIAL EQUIVALENCE:

CERDAK™ is substantially equivalent in the intended use to WoundStat (K071936)

CERDAK™ has been evaluated for its biocompatibility which meets requirements as stipulated in ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

CERDAK™ has the same intended use as the primary predicate device as they are both intended to cover a wound.

Data presented in this submission substantiates equivalence of CERDAK™ to the predicate device.

PERFORMANCE TESTING:

CERDAK™ dressing has been subjected to testing to assess the Biocompatibility, as well as the physical performance of the device.

CERDAK™ was evaluated through in-vitro and animal safety studies.

Safety tests and the conclusions drawn for the test articles:
CERDAK ™ was evaluated through in-vitro and animal safety studies.

Safety tests and the conclusions drawn for the test articles:

1. Cytotoxicity: (Balb/c/3T3/ cells in-vitro condition using elution method)
CERDAK ™ is non-cytotoxic and meets the requirements of the Test defined in ISO 10993-5 guidelines.

2. Primary Skin Irritation Test: Irritation (New Zealand white rabbits)
CERDAK™ is considered a negligible irritant after a single topical application to the skin of New Zealand White rabbits.

3. Skin Sensitization :(Guinea Pig Maximization Test - GPMT)
No mortality and morbidity were observed in any of the animals used in the study. No skin sensitization reactions were observed in both control and test sites of all the animals. CERDAK™ was found to be non-sensitizer.

The biocompatibility of CERDAK™ has been demonstrated through appropriate *in vivo* and *in vitro* tests. The product has been assessed in accordance with ANSI/AAM I/ISO 10993 and does not introduce any additional safety risk. The bench testing includes visual inspection, weight and thickness of final product packaging testing.

CLINICAL STUDY:

A clinical study was conducted on CERDAK™ using normal saline as control. Results of culture and sensitivity test showed there was no statistically significant difference in infection rate and infection type between both the groups. There was no statistical difference in complications among both the groups. CERDAK™ was found to be safe in covering the wounds and creating a moist wound environment.