DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 24, 2014

Core Scientific LTD.
Dr. Sigalit Ariely-Portnoy
Gsap LTD.
POB 3
22806, Shave-Zion
Israel

Re: K140573
Trade/Device Name: WoundClot Hemostatic Gauze
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 13, 2014
Received: October 21, 2014

Dear Dr. Ariely-Portnoy:

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" (21CFR 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 yours,

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Kl40573

Device Name
WoundClot Hemostatic Gauze

Indications for Use *(Describe)*
WoundClot Hemostatic Gauze is intended to be used as a topical dressing for local management of bleeding wounds, such as cuts, lacerations and abrasions, and for use as a temporary treatment of severely bleeding wounds, such as surgical wounds (operative, postoperative, donor sites, dermatological) and traumatic injuries.

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

I. SUBMITTER

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Date Prepared: November 19, 2014.

II. DEVICE

Name of Device: WoundClot Hemostatic Gauze
Common or Usual Name: Hemostatic Gauze
Classification Name: Dressing, Wound, Drug
Regulatory Class: Unclassified Medical Device
Product Code: FRO

III. PREDICATE DEVICE

BenaCel Hemostatic Gauze, K080532
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Core Scientific Creations WoundClot Hemostatic Gauze device is made from regenerated cellulose, chemically treated to become water-soluble. When the regenerated cellulose contacts blood and exudates, it expands and forms into gel, adheres and creates pressure to seal wound.

V. INDICATIONS FOR USE

Prescription Use: WoundClot Hemostatic Gauze is intended to be used as a topical dressing for local management of bleeding wounds, such as cuts, lacerations and abrasions, and for use as a temporary treatment of severely bleeding wounds, such as surgical wounds (operative, postoperative, donor sites, dermatological) and traumatic injuries.

There are no differences between WoundClot Hemostatic Gauze and the predicate device's intended use.
The Indication for Use statement for WoundClot Hemostatic Gauze is identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

WoundClot Hemostatic Gauze is substantially equivalent to the legally marketed BenaCel Hemostatic Gauze (k080532) in composition, design and processing.

The indications for use and technological characteristics of the WoundClot Hemostatic Gauze device are substantially equivalent to the indications for use and technological characteristics of the predicate BenaCel.

The chemical composition (regenerated cotton cellulose) of the WoundClot Hemostatic Gauze device is similar to the chemical composition of the predicate BenaCel device. The principle of operation of the WoundClot Hemostatic Gauze is substantially equivalent to that of the BenaCel device; both transform into a gel, covering and protecting the wound while hemostasis is being achieved.

The physical performance specifications of the WoundClot Hemostatic Gauze device are substantially equivalent to those in the BenaCel device. Patient contact materials are also similar.

Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The Intended Use of the WoundClot Hemostatic Gauze puts it within the biocompatibility category of limited contact duration, and an external communicating device.
Biocompatibility testing for the WoundClot gauze device were performed in compliance with the following international standards:

- Cytotoxicity (per ISO 10993-5:2009)
- Irritation/ ISO Intracutaneous (per ISO 10993-10:2010)
- Sensitization (per ISO 10993-10:2010)
- Acute Systemic Toxicity (per ISO 10993-11:2006)

Non-Clinical (Bench) Testing:

The similarity of the chemical and physical properties and modifications was shown by comparative performance bench tests between WoundClot Hemostatic Gauze and the predicate device including physical appearance, weight and density, conductivity, pH, solubility, dissolution profile, FTIR analysis and Degree of Substitution test.

Animal Study:

The animal model for the clinical study was a femoral arteriotomy in swine. In this study, 10, 35-38 Kg Large white Landrace cross-bred (male) swine, with normal coagulation functions were tested on the right femoral artery. 5 animals were tested with the WoundClot device and 5 animals were tested with the BenaCel device.

The primary end points of the study were mean arterial pressure (MAP), survival time, percentage survival, bleeding/hemostasis time (time period necessary for bleeding to stop) and post-treatment blood loss. The secondary end points were measurements of hemoglobin, hematocrit, platelet counts, pH, base deficit and coagulation values (PT, aPTT, fibrinogen, and TEG parameters). In addition, histology analysis was conducted and showed similarities in the pathological findings between the WoundClot and the predicate device.

This study has demonstrated that WoundClot is equivalent to Benacel Hemostatic Gauze in achieving hemostasis in a severe bleeding animal model.

VIII. CONCLUSIONS

Taken together, the technological characteristics, the indications for use and the performance data including bench testing and pre-clinical animal testing, demonstrate that WoundClot Hemostatic Gauze is as safe and as effective as the predicate device, hence both devices are substantially equivalent.