Core Scientific Creation Ltd.
% Sigalit Ariely-Portnoy, Ph.D.
CEO & Founder
Gsap Ltd.
POB 3, Shave-Zion
22806 Israel

April 21, 2023

Re: K160679
Trade/Device Name: WoundClot
Regulatory Class: Unclassified
Product Code: QSY

Dear Sigalit Ariely-Portnoy, Ph.D.:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 8, 2016. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSY.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 8, 2016

Core Scientific Creation Ltd.
% Sigalit Ariely-Portnoy, Ph.D.
GSAP Ltd.
POB 3, Shave-Zion
22806 Israel

Re: K160679
Trade/Device Name: Woundclot
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 19, 2016
Received: July 29, 2016

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" (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 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)*
K160679

Device Name
WoundClot

Indications for Use *(Describe)*
WoundClot is intended to be used as a topical dressing for minor skin surface bleeding wounds such as 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

Company Name: Core Scientific Creations Ltd.

Address: Yohanan Hasandlar 4 St.
Kfar Saba POB 2270 .4464102 Israel
Tel: +972-9-7881919
Fax: +972-9-7790263

Contact Person: Dr. Sigalit Ariely-Portnoy

Company Name: Gsap Ltd.

Address: POB 3, Shave-Zion 22806, Israel
Tel: +972-4-9520995
Fax: +972-4-6359852

Date Prepared: August 2nd, 2016.

II. DEVICE

Name of Device: WoundClot

Common or Usual Name: Hemostatic wound dressing

Classification Name: Dressing, Wound, Drug

Regulatory Class: Unclassified Medical Device

Product Code: FRO

III. PREDICATE DEVICE

1. Primary Predicate: LifeScience PLUS, Inc, BloodSTOP and BloodSTOP iX Hemostatic Gauze K071578.
2. Core Scientific Creations Ltd., WoundClot Hemostatic Gauze, K140573.

The predicates have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

Core Scientific Creations WoundClot device is water soluble, based on cellulosic structure. In contact with liquids it forms an adhesive gel which expands and adheres to the wound for bleeding control.

V. INDICATIONS FOR USE

WoundClot is intended to be used as a topical dressing for minor skin surface bleeding wounds such as minor cuts and minor abrasions.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

WoundClot has the same intended use as the predicate devices, BloodSTOP and BloodSTOP iX Hemostatic Gauze and WoundClot Hemostatic Gauze. All devices are intended for hemostatic wound dressing.

The indications for use of the WoundClot device are similar to the indications for use listed for the primary predicate BloodSTOP and BloodSTOP iX Hemostatic Gauze, which is OTC use as topical dressing for local management of skin surface bleeding wounds.

The chemical composition (modified cellulose) of the WoundClot device is similar to the chemical composition of its predicate devices. Additionally, the mechanism of action of the WoundClot device is substantially equivalent to that of the BloodSTOP and BloodSTOP iX Hemostatic Gauze and the WoundClot Hemostatic Gauze device; all devices transform into gel, covering and protecting the wound while hemostasis is being achieved.

VII. PERFORMANCE DATA

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

Biocompatibility Testing

The Intended Use of the WoundClot puts it within the biocompatibility category of limited contact duration, and an external communicating device.

Biocompatibility testing for the WoundClot device were performed in compliance with the following international standards:

- Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (per ISO 10993-1:2009)
- Cytotoxicity Study Using the ISO Elution Method (per ISO 10993-5:2009)
- ISO Skin Irritation Study in Rabbits (per ISO 10993-10:2010)
- ISO Guinea Pig Maximization Sensitization Test (per ISO 10993-10:2010)
- Systemic Toxicity Study in Mice (per ISO 10993-11:2006)

Non-Clinical (Bench) Testing:

The physical characteristics of WoundClot and its predicate, BloodSTOP and BloodSTOP iX Hemostatic Gauze were compared and found to have substantial equivalent physical properties such as color, odor, uniformity softness, weight, pH, solubility and dissolution behavior.

The solubility results described in the test report demonstrates that WoundClot device is completely soluble in water and can be easily rinsed and removed from the wound.

VIII. CONCLUSIONS

Taken together, the intended use, the technological characteristics and the performance data, demonstrate that WoundClot device is as safe and as effective as the predicate devices, hence the devices are substantially equivalent.