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

June 3, 2015

BioTD, S.A.
% Mr. Richard Gillis, Ph.D.
Emergo Group
816 Congress Avenue, Suite 1400
Austin, Texas 78701

Re: K141637
Trade/Device Name: SPB Skin Emulsion
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 28, 2015
Received: April 30, 2015

Dear Dr. Gillis:

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)*
K141637

Device Name

SPB Skin Emulsion

Indications for Use *(Describe)*

Prescription Use:

As a prescription topical skin care emulsion to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic and allergic contact dermatitis. SPB helps maintain a moist wound & skin environment, which is beneficial to the healing process.

Over-The-Counter Use:

An OTC topical skin care emulsion to relieve the burning and itching associated with many common types of skin irritation. SPB helps maintain a moist wound & skin environment, which is beneficial to the healing process.

Type of Use *(Select one or both, as applicable)*

[x] Prescription Use (Part 21 CFR 801 Subpart D) [x] Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
for
SPB Skin Emulsion

1. Submission Sponsor

BioTD, S.A.
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Heredia
Costa Rica
Phone: 1 501 868 8300
Fax: N/A
Contact: Robin Wiscovitch, Ph.D, Chief Executive Officer

2. Submission Correspondent

Emergo Group
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Austin, TX 78701
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Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Richard Gillis, PhD, Senior Consultant
Email: project.management@emergogroup.com

3. Date Prepared

June 16, 2014

4. Device Identification

Trade/Proprietary Name:	SPB Skin Emulsion
Common/Usual Name:	Wound gel
Classification Name:	Dressing, Wound, Drug
Classification Regulation:	Not specified
Product Code:	FRO
Device Class:	Unclassified (Pre-Amendment)
Classification Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

MimyX™ Cream (K041342)

6. Device Description

SPB Skin Emulsion is a topical skin care emulsion that is indicated to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic and allergic contact dermatitis. SPB Skin Emulsion contains natural extracts to moisturize the skin.

7. Rx Indications for Use Statement:

As a prescription topical skin care emulsion to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic and allergic contact dermatitis. SPB helps maintain a moist wound & skin environment, which is beneficial to the healing process.

OTC Indications for Use Statement:

An OTC topical skin care emulsion to relieve the burning and itching associated with many common types of skin irritation. SPB helps maintain a moist wound & skin environment, which is beneficial to the healing process.

8. Substantial Equivalence Discussion

The following table compares the SPB Skin Emulsion to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**BioTD, S.A.**	**Stiefel Laboratories, Inc.**	**Significant Differences**
Trade Name	SPB Skin Emulsion	MimyX™ Cream	
510(k) Number	Not assigned	K041342	N/A
Product Code	FRO	MGQ	None
Regulation Number	Unclassified	Unclassified	None
Regulation Name	Dressing, Wound, Drug	Dressing, Wound & Burn, Hydrogel with Drug and/or Biologic	None
Indications for Use, Rx	As a prescription topical skin care emulsion to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic and allergic contact dermatitis. SPB helps maintain a moist wound & skin environment,	Under the supervision of a healthcare professional, MimyX Cream is indicated to manage and relieve the burning and itching experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis and allergic contact	None

Manufacturer	**BioTD, S.A.**	**Stiefel Laboratories, Inc.**	**Significant Differences**
Trade Name	SPB Skin Emulsion	MimyX™ Cream	
	which is beneficial to the healing process.	dermatitis. MirnyX Cream helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.	
Indications for Use, OTC	An OTC topical skin care emulsion to relieve the burning and itching associated with many common types of skin irritation. SPB helps maintain a moist wound & skin environment, which is beneficial to the healing process.	MirnyX Cream helps to nourish skin and relieve the burning and itching associated with many common types of skin irritation. MimyX Cream may also be used to soothe minor burns, including sunburn.	None
Material			
Solvent	Deionized water	purified water	None
Oils	Natural African palm oils	Olive oil, glycerin, palm glycerides, vegetable oil, lecithin, squalene, betaine, sacrosine, acetamide MEA	Similar; all ingredients are moisturizers and skin conditioners.
Polymerizing/ Thickening agents	Copolymer	Hydroxyethylcellulose, sodium carbomer, carbomer, xanthan gum, Palmitamide MEA, pentylene glycol (PTG)	Similar; all are common thickeners, emulsifiers, and gel and film formers
Preservative	Silver nanoparticles	None	Different; The silver nanoparticles are a preservative and do not interact with the skin. Biocompatibility results show no effect on safety.
Fragrance	Eucalyptus oil	None	Different; Eucalyptus oil is a natural fragrance added for marketing purposes only. Biocompatibility results show no effect on safety.
Sterile	No	No	None
Single-Use	Yes	Yes	None
Shelf Life	3 years	18 months	None
Complies with ISO 10993-1	Yes	Yes	None

9. Non-Clinical Performance Data

The following testing has been performed to support substantial equivalence:

- Cytotoxicity Assay (ISO 10993-5:2010). The test product extract showed no cytotoxic potential.
- Sensitization Test (ISO 10993-10:2012). The test substance was non-sensitizing.
- Irritation Test (ISO 10993-10:2012). SPB Skin Emulsion was determined to be non-irritating.

As part of demonstrating safety and effectiveness of SPB Skin Emulsion and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, BioTD, S.A. completed a number of tests. The SPB Skin Emulsion meets all the requirements for overall design and biocompatibility, which confirm that the outputs meets the design inputs and specifications. The SPB Skin Emulsion passed all testing stated above as shown by the acceptable results obtained.

10. Clinical Performance Data

There are no new innovative aspects that have been introduced with this device. Clinical testing was performed only to establish substantial equivalence to the predicate device. Performance of SPB Skin Emulsion was compared that of the predicate MimyX™ Cream. A double-blind study was designed with a limited number of volunteers with acute contact dermatitis. Daily observations of redness and itching were recorded by trained personnel after exposure to a known allergen during routine work-related activities. SPB Skin Emulsion performed similarly to the predicate with no observable events of either redness or itching, and the placebo showing no positive effects. These types of devices, including the predicate, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the SPB Skin Emulsion and the predicate device do not raise any questions regarding its safety and effectiveness. The SPB Skin Emulsion, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.