NeilMed®

K123910

Attachment 5

510(k) SUMMARY
(As prepared in accordance with 21 CFR 807.87(h) and 21 CFR 807.92)

Date Prepared: December 4th 2012

1. Submitter's Name, Address, Telephone Number, Contact Person
NEILMED PHARMACEUTICALS, INC.
Address: 601 Aviation Blvd, Santa Rosa, CA 95403
Contact: **Phone: +1 707 525 3784** **Fax: +1 707 525 3785** OCT 2 9 2013
Contact Person: Dr Ketan Mehta Ketan@neilmed.com
2. Name of Device and Name/Address of Sponsor
Device: Dr. Mehta's Wound Wash Saline Spray™
Name of Sponsor: NEILMED PHARMACEUTICALS, INC.
Address: 601 Aviation Blvd, Santa Rosa, CA 95403
3. Common or Usual Name
Wound Cleanser
4. Device Classification Name and Classification Code
Name: Dressing, Wound, Drug
Code: FRO
Review Panel: General & Plastic Surgery
Device Class: Unclassified
5. Description
Dr. Mehta's Wound Wash Saline Spray™ consists of drug and preservative-free sterile isotonic saline solution that is delivered in atomized spray form by means of activating the actuator. Dr. Mehta's Wound Wash Saline Spray™ distributed as a single can includes 0.9% saline (sodium chloride) solution. The product utilizes bag-on-valve technology (bag in can). The propellant, compressed air, is charged into the container between bag and the can creating a means to dispense the contents of the bag, i.e., sterile isotonic saline solution. The product consists of specially designed actuator to deliver an effective consistent spray of the solution on the wound area. The filled device is sterilized by gamma radiation utilizing parameters those are validated according to ISO/AAMI 11137 requirements (Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization). The product passes USP<71> Sterility Test. Dr. Mehta's Wound Wash Saline Spray™ is available as an over-the-counter product, and will be labeled with the following indication: "To cleanse minor wounds and scrapes.".
6. Predicate Devices
Wound Wash Saline® (K083355) (Blairex Laboratories, Inc.)
7. Intended Use / Indications for Use

Indications for OTC Use :

"To cleanse minor wounds and scrapes".

The product is not to be used for body cavities, canals, eyes, or mouth.

8. Technological Characteristics

Dr. Mehta's Wound Wash Saline Spray™ consists of an aerosol bag on valve technology which includes a bag-in-can system attached to actuator for spray dispensing in all positions. The bag is a laminate system including sandwiched aluminum layer providing an impermeable barrier between the propellant (compressed air) and the sterile saline solution within the bag. The solution comes in contact with the inner layer (polypropylene) of the bag. 0.9% sterile saline solution is colorless and consists of USP grade sodium chloride and USP grade purified water. The propellant, compressed air, is charged into the container between bag and the can creating a means to dispense the contents of the bag, sterile isotonic saline solution. The device manufacturing process includes crimping, pressure testing and filling and packaging for sterilization which is followed by gamma sterilization. The product is tested against established specifications and meets USP<71> sterility requirements. The technological characteristics of the subject device are substantially equivalent to those of the predicate device.

9. Substantial Equivalence

Dr. Mehta's Wound Wash Saline Spray™ is as safe as the predicate device. It has the same technological characteristics and basic principles of operation as its predicate device. The technological characteristics with respect to the spray including pressurization method, bag technology and sterilization are the same as the predicate device.

The non-clinical tests performed on the subject device include (i) USP <71> Sterility Test, (ii) LAL Test, & (iii) MEM Elution Test. The subject device passes USP <71> Sterility Test, like the predicate device. The subject device also passes LAL Test or Bacterial Endotoxins Test, & MEM Elution Test or Cytotoxicity Test.

Thus, Dr. Mehta's Wound Wash Saline Spray™ is substantially equivalent to the predicate device.

This concludes the 510(k) Summary.

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

October 29, 2013

NeilMed Pharmaceuticals, Incorporated
% Mr. Dinesh Patel
Vice President of Quality Assurance and Regulatory Affairs
601 Aviation Boulevard
Santa Rosa, California 95403

Re: K123910
Trade/Device Name: Dr. Mehta's Wound Wash Saline Spray
Regulation Name: Dressing, Wound, Drug
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 26, 2013
Received: August 28, 2013

Dear Mr. Patel:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 Mark N. Melkerson
Acting 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K123910

Device Name
Dr. Mehta's WoundWash Saline Spray(TM)

Indications for Use *(Describe)*

To cleanse minor wounds and scrapes.

The product is not to be used for body cavities, canals, eyes, or mouth.

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)

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)*

Jiyoung Dang -S