



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

June 2, 2016

Medical Technology Research, Inc.
Bhalchandra M. Karandikar, Ph.D
Chief Technology Officer
2650 Progress Way
Woodburn, OR 97071

Re: K152519

Trade/Device Name: MTR550 (Tentative) Antimicrobial Silver Wound Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 25, 2016
Received: May 5, 2016

Dear Dr. Karandikar:

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,


Jennifer R. Stevenson -A

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

INDICATIONS FOR USE

K NUMBER: **K152519**

DEVICE NAME: **MTR550 ANTIMICROBIAL SILVER WOUND GEL**

INDICATIONS FOR USE

For the management of dry to low/moderate exuding wounds such as:

Stage I-IV pressure ulcers

Diabetic & foot ulcers

Partial and full thickness wounds

Graft and donor sites

Post-operative surgical wounds

Trauma wounds (dermal lesions, trauma injuries and incisions)

1 & 2nd degree burns

Abrasions and lacerations

TYPE OF USE: **Prescription Use Only (Part 21 CFR 801 Subpart D)**

510(k) SUMMARY

1. SUBMITTER/OWNER

MEDICAL TECHNOLOGY RESEARCH INC.
2650 PROGRESS WAY
WOODBURN, OR 97071

Phone: 503-902-6279
Fax: 503-980-7931

Contact Person: Bhalchandra M. Karandikar, PhD
Chief Technology Officer

Date Prepared: April 25, 2016

2. DEVICE

Name of Device: MTR550 (Tentative) Antimicrobial Silver Wound Gel
Common Name: Antimicrobial Wound Dressing
Classification Name: Dressing Wound, Drug
Regulatory Class: Unclassified
Product Code: FRO

3. PREDICATE DEVICE

MTR550 gel is substantially equivalent to the following legally marketed predicate devices:

- (i) SilverShield™ Antimicrobial Skin and Wound Gel (# K062212) from Anacapa Technologies of San Dimas, CA and distributed presently under SilverSept® name
- (ii) Silver Antimicrobial Wound Gel from Advanced Medical Solutions of Winsford, UK (#K110458) and marketed by Molyntyke under the name Normlgel Ag®

4. DEVICE DESCRIPTION

The product is a spreadable amorphous water based wound gel comprising a synthetic clay as the thickening agent. The gel provides for optimal moisture management of the wound bed by donating/absorbing water that in turns aids in wound healing. The presence of active silver compounds within the gel provides preservative action and acts as an effective barrier to microbial penetration by inhibiting the growth of microorganisms within the dressing. The gel is clear to hazy and will not stain the skin tissue when used over a period of 3 days though its potential to stain skin beyond 3 day use is not known.

Even with silver content at 550ppm, the gel is not discolored by incidental exposure to intense light such as sunlight or to elevated environment temperatures.

The device is packaged primarily in tamperproof tubes (43g) with screw caps though it may be available in other sizes and containers. The tube is contained in a cardboard box with product insert.

5. INDICATIONS FOR USE

The device is indicated for use by prescription only. It is indicated for use in the management of dry to low/moderate exuding partial and fullness thickness wounds, stage I-IV pressure ulcers, diabetic and foot ulcers, graft wounds and donor sites, first and second degree wounds, post-operative surgical wounds, trauma wounds (dermal lesions, trauma injuries and incisions), abrasions and lacerations.

Contraindications: The gel should not be used on patients with known sensitivity to silver and s-triazine compounds.

6. MANUFACTURING

The MTR550 gel will be manufactured in a production facility in accordance with good manufacturing practices consistent with US FDA guidelines. The batch production of the gel and packaging will be verified to meet product specifications to ensure the product is safe and effective.

7. BIOCOMPATIBILITY TESTING

The device has been tested for in-vitro cytotoxicity, dermal irritation and sensitization in accordance with ISO 10993 -1 (Biological Evaluation of Medical Devices).

No systemic toxicity was associated with the antimicrobial silver compounds. Animal study employing rats showed no adverse effects on animals due to the device.

8. PERFORMANCE

The antimicrobial efficacy of the device has been demonstrated by 28 days Antimicrobial preservative challenge test in accordance with USP Chapter 51 guidelines. Employing in vitro assays, the antimicrobial barrier property was demonstrated against 17 different micro-organisms that included bacteria, yeast and fungi. The tested micro-organisms included, MRSA, VRE, Candida A. and Aspergillus niger. Sustainance of antimicrobial barrier activity was demonstrated for 3 days in a serial transfer assay.

Animal study employing rats showed the device exhibited no adverse effect on animals. In a porcine study examining deep partial thickness burn wound healing, MTR550 device was found to be safe and effective as the predicate device.

Despite its silver content at 550ppm, the device was shown to be non-staining to dermal tissue over 3 days use. The device showed no discoloration despite exposure to intense light or elevated environmental temperatures.

9. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

With respect to its physical and chemical properties, the device is substantially equivalent to the predicate device.

The mechanism of antimicrobial action is also similar. Both device exert toxicity towards micro-organisms as a result of silver ions.

The device is substantially equivalent to legally marketed predicate devices in composition and intended use.

10. CONCLUSIONS

Based on the indications for use, biocompatibility, invivo studies, performance data, the MTR550 gel is substantially similar to SilverShield™ Antimicrobial Skin and Wound Gel (#K062212)