

510(k) SUMMARY**ProThelial™ & Orafate Sucralfate Malate Paste****1. Submission Applicant & Correspondent**

Submission Date:	December 18, 2012
Revision Date:	March 12, 2013 July 22, 2013
Name:	Mueller Medical International LLC
Address:	48a Moosup Valley Road Foster RI 02825 USA
Phone No:	401-397- 6203
Contact Person:	Ricky W. McCullough MD

AUG 07 2013

2. Name of Device

Common or Usual Name:	Sucralfate Malate Paste
Trade/Proprietary/Model Name:	ProThelial™ & Orafate Sucralfate Paste
Classification Name:	Dressing, Wound, Drug
Product Code:	FRO
Classification:	Unclassified

3. Devices to Which New Device is Substantially Equivalent

ProThelial™ & Orafate Sucralfate Paste is a hydrogel wound dressing that is substantially equivalent to K043587 Sucralfate HCl Topical Paste and K082856 Carapaste® Oral Wound Dressing. Its substantial equivalence is based firstly on sucralfate being the active ingredient for each of the devices without which neither device would be operative as wound dressings.

Additionally, similar to its predicate devices, the present device requires the polymerization of sucralfate in order to function. Lastly both the present device and the predicate devices have the identical Indication of Use.

4. Device Description

ProThelial™ & Orafate Sucralfate Paste is an amorphous hydrogel paste formed by the controlled reaction of sucralfate with a limited quantity of malic acid and calcium carbonate solution. The amorphous hydrogel paste formed by this reaction binds reversibly to wounds and is intended to form a protective film that covers wounds, protects against further irritation and relieves pain. ProThelial™ & Orafate Sucralfate Paste may be administered directly to an accessible oral wound to provide an adherent physical covering of the wound bed. Although prepared by reaction of sucralfate with an acid, the polymerized sucralfate self-buffers to a pH 5.0 – 7.0.

5. Intended Use of the Device

ProThelial™ & Orafate Sucralfate Malate Paste forms a protective layer over the oral mucosa by adhering to the mucosal surface which allows it to protect against further irritation and relieve pain. The paste may be used in the management of mouth lesions of all types including aphthous ulcer, stomatitis, mucositis, minor lesions, chafing and traumatic ulcers, abrasions caused by braces and ill fitting dentures, and lesions associated with oral surgery.

6. Summary of Technological Characteristics of the Device Compared to the Predicate Devices

As seen in table below, there is no difference between the subject and predicates with respect to indications for use or technology.

Product Name	ProThelial™ & Orafate	Sucralfate Topical Paste	Sucralfate HCl Topical Paste
Device Number	K123904	K082856	K043587
Patient Group	Pediatric & Adult	Pediatric & Adult	Pediatric & Adult
Method of Use	Pre-Mixed with Malic Acid & Calcium Carbonate	Pre-Mixed with HCl Acid	Mix with HCl at time of use
Administrations per day	Application to mucosal wounds 2 -3 times daily	As Needed for Application to mucosal wounds	As Needed for Application to mucosal wounds
Claim	Management and relief of pain, non irritating, safe if swallowed	Management and relief of pain, non irritating, does not sting, safe if swallowed	Management and relief of pain, non irritating, does not sting, safe if swallowed
Area of Use	Oral Mucosa	Oral Mucosa	Oral Mucosa
Indication	Oral lesions of all types including aphthous ulcer, stomatitis, mucositis, traumatic ulcers, abrasions, wounds from oral surgery To form a protective layer over the mucosa by reversibly adhering to the surface allowing relief of pain and protection against further irritation.	Oral lesions of all types including aphthous ulcer, stomatitis, mucositis, traumatic ulcers, abrasions, wounds from oral surgery To form a protective layer over the mucosa by reversibly adhering to the surface allowing relief of pain and protection against further irritation.	Oral lesions of all types including aphthous ulcer, stomatitis, mucositis, traumatic ulcers, abrasions, wounds from oral surgery To form a protective layer over the mucosa by reversibly adhering to the surface allowing relief of pain and protection against further irritation.
Type of Product	Paste	Paste	Paste
Presentation	Non Sterile	Non Sterile	Non Sterile

ProThelial™ & Orafate Sucralfate Paste forms a protective layer over the oral mucosa, adhering to the mucosal surface, relieving pain and and irritation. The predicate devices, K082856 and K043587 use Hydrochloric acid, a strong acid, to effect polymerization of sucralfate.

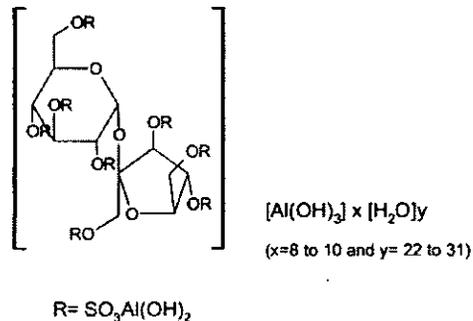
Unlike predicate devices, the present device contains nine components each of which purposefully contribute to the operation of the device. Sucralfate is the sole active conveying protective cover for the oral mucosa. Malate and calcium carbonate facilitate the polymerization of sucralfate in water. The water provide matrix for the polymerization of sucralfate and a vehicle to hold polymerized sucralfate in place when applied. Xanthan gum and calcium sulfate provide the paste consistency for

the device. Sodium saccharin maintains agreeable palatability of the device while methyl and propyl parabens preserve a microbial-static condition for the paste during its shelf life.

7. Conclusions

Both the present device and predicate devices use sucralfate as the active component to achieve their clinical effect. Each of the devices requires the facilitated polymerization of sucralfate in order for the devices to function. Each of the devices requires direct application, transient contact with the patient and multiple administrations for their use. Proper operation of each of the devices requires muco-adherence of sucralfate.

The non-clinical performance data relied on in this submission for a determination of substantial equivalence is the identical nature of clinically effective component of this and the predicate devices. The clinically effective component is sucralfate USP, without which neither device would function. The non-clinical tests involve those required by USP national standards to verify the presence sucralfate. Sucralfate used in each of the devices is an α -D-glucopyranoside, β -D-fructofuranosyl-, octakis-(hydrogen sulfate), aluminum complex, molecular weight of 2,086.75 having the following structure:



The physical wound covering properties of ProThelial™ & Orafate Sucralfate Paste would be expected to be at least as effective as those of the predicate devices.

No new biocompatibility or other safety issues are raised.

From the nonclinical tests discussed above the subject device is as safe, as effective, and performs as well as the predicate devices.

The manufacturer of record concludes from the comparison of clinically effective components of this device and the predicate devices that the current device, ProThelial™ & Orafate are substantially equivalent to predicate devices K0435897 and K082856.



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

Ricky W. McCullough, MD
Managing Director
Mueller Medical International LLC
48a Moosup Valley Road
Foster, Rhode Island 02825

August 7, 2013

Re: K123904

Trade/Device Name: ProThelial™ & Orafate™ Sucralfate Malate Paste

Regulatory Class: Unclassified

Product Code: FRO

Dated: July 15, 2013

Received: July 17, 2013

Dear Dr. McCullough:

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.

Page 2 – Ricky W. McCullough, MD

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" (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 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,
FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123904

Device Name: ProThelial™ & Orafate Sucralfate Malate Paste

Indications For Use:

ProThelial™ & Orafate Sucralfate Malate Paste forms a protective layer over the oral mucosa by adhering to the mucosal surface which allows it to protect against further irritation and relieve pain. The paste may be used in the management of mouth lesions of all types including aphthous ulcer, stomatitis, mucositis, minor lesions, chafing and traumatic ulcers, abrasions caused by braces and ill fitting dentures, and lesions associated with oral surgery.

Prescription Use X AND/OR Over-The-Counter Use
 (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

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(Division Sign-Off)
 Division of Surgical Devices
 510(k) Number: K123904