K043587½

510K Summary
Sucralfate HCl Topical Paste™

FEB 3 2006

1. Submission Applicant & Correspondent

Submission Date	December 17, 2004
Name:	Patrick D. McGrath, Ph.D.
Address:	1471 Greystone Drive Gurnee, IL 60031
Phone No:	(847)-543-4138
Contact Person	Patrick D. McGrath, Ph.D.

2. Name of Device

Common or Usual Name: Sucralfate HCl Topical Paste™

Trade/Proprietary/Model Name: The following Trade Names will be used:
Katen Paste ™ Kit
Sucralfate Paste Kit ™

Classification Name: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic

Product Code: ~~MGQ~~ FRO

Classification: Unclassified

3. Devices to Which New Device is Substantially Equivalent

Gelclair Concentrated Oral Gel K013056
Salicept Oral Patch K012126

4. Device Description

Sucralfate HCl Topical Paste ™ is an amorphous hydrogel paste formed by the controlled reaction of sucralfate with a limited quantity of hydrochloric acid. This compounding process is intended for execution by a pharmacist, dentist, physician, podiatrist, veterinarian, other licensed prescriber or supervised staff trained to handle HCl 1.0N. The amorphous hydrogel paste formed by this reaction is intended to form a protective film that covers lesions where gastric acid or local wound bed acidity is not available or inconsistently present.

Sucralfate is reacted with HCl 1.0N in a ratio of approximately of 5 - 8 mL HCl per 5 gram sucralfate. Increased proportions of HCl produce thinner pastes. When reacted with hydrochloric acid sucralfate forms an amorphous hydrous gel that binds reversibly to wounds. Although reacted with strong acid, the polymerized sucralfate self-buffers to a pH of approximately 3.8. The sucralfate paste formed by this reaction may be administered directly to an accessible wound to provide an adherent physical covering of the wound bed.

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5. Intended Use of the Device

Sucralfate HCl Topical 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

Sucralfate HCl Topical 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. Multiple clinical studies demonstrate that the safety and effectiveness of topical sucralfate is at least equivalent to that of the identified predicate devices in those uses. In view of the long history of safe use of sucralfate in oral doses up to 4 grams daily and with no new adverse reactions reported after use of sucralfate applied topically, no new biocompatibility or other safety issues are raised.

7. Conclusions

The physical properties of the prepared sucralfate polymer would be expected to be at least as effective as those of the predicate devices. Since the safety of sucralfate taken orally as a drug in doses up to 4 gram daily has been well established, no new biocompatibility or other safety issues are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

Patrick D. McGrath, Ph.D.
1471 Greystone Drive
Gurnee, Illinois 60031

Re: K043587
Trade/Device Name: Sucralfate HCl Topical Paste
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 7, 2006
Received: January 10, 2006

Dear Dr. McGrath:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043587

Indications for Use

510(k) Number (if known): K043587

Device Name: Sucralfate HCl Topical Paste

Indications For Use:

Sucralfate HCl Topical 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. This 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___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043587