OCT 15 2008

510K Summary
CARAPASTE® Oral Wound Dressing
K082856

1. Submission Applicant & Correspondent

Submission Date	September 25, 2008
Name:	McGrath Pharmaceuticals, Inc.
Address:	683 Center Street Unit C Grayslake, IL 60030
Phone No:	(847)-548- 7860
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:

CARAPASTE® Oral Wound Dressing

Classification Name: Dressing, Wound, Drug

Product Code: FRO

Classification: Unclassified

3. Devices to Which New Device is Substantially Equivalent

Sucralfate HCl Topical Paste K043587

4. Device Description

CARAPASTE ® Oral Wound Dressing, Sucralfate HCl Topical Paste, is an amorphous hydrogel paste formed by the controlled reaction of sucralfate with a limited quantity of hydrochloric acid. The amorphous hydrogel paste formed by this reaction binds reversibly to wounds and is intended to form a protective film that covers lesions where gastric acid or local wound bed acidity is not available or is inconsistently present. CARAPASTE ® Oral Wound Dressing 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 strong acid, the polymerized sucralfate self-buffers to a pH of approximately 3.5.

5. Intended Use of the Device

CARAPASTE® Oral Wound Dressing 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

CARAPASTE® Oral Wound Dressing forms a protective layer over the oral mucosa, adheres to the mucosal surface and relieves pain and promotes wound healing of mouth lesions.

7. Conclusions

The physical wound covering properties of CARAPASTE® Oral Wound Dressing would be expected to be at least as effective as those of the predicate devices. 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

OCT 15 2008

McGrath Pharmaceuticals, Inc.
% Patrick D. McGrath Ph.D.
President and Founder
683 Center Street, Unit C
Grayslake, Illinois 60030

Re: K082856
Trade/Device Name: CARAPASTE® Oral Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 25, 2008
Received: September 29, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K082856

Device Name: CARAPASTE® Oral Wound Dressing

Indications For Use:

CARAPASTE® Oral Wound Dressing 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___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkm

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

510(k) Number K082856