AUG - 6 2001

GEBAUER COMPANY

Pharmaceutical Preparations

K981693

510(k) SUMMARY

Establishment Name:	Gebauer Company (Specification Developer of Salivart®)
Address:	9410 St. Catherine Ave. Cleveland, OH 44104
Phone Number:	(216) 271-5252
Fax Number:	(216) 271-0910
Contact Person:	Denise E. Spellman (Official Correspondent)
Date Summary Prepared:	5/12/98
Device Name:	Salivart® Oral Moisturizer
Classification Name:	Artificial Saliva
Predicate Product:	MOI-STIR® Mouth Moistener

Device Description:

Salivart® Oral Moisturizer, an OTC device, is an aqueous electrolyte solution containing a viscosity agent and an emulsifier. The solution is aerosolized with a nitrogen propellant. It comes in two different can sizes. The smaller size is both sold and used as a promotional sample.

Intended Use of Device:

An oral moisturizer which temporarily relieves the discomfort of dry mouth (xerostomia) and dry throat naturally. Salivart may be used to replace human saliva, when the amount of saliva normally secreted has been reduced. Salivart lubricates the mouth and throat to soothe discomfort and assist in speaking and swallowing. Salivart relieves dry mouth caused by certain medications, therapeutic treatments, diseases, normal aging and emotional factors.

9410 ST. CATHERINE AVE. • CLEVELAND, OHIO 44104 • PHONE 216-271-5252 • FAX 216-271-5335 • TOLL FREE 1-800-321-9348

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Moi-Stir® Mouth Moistener and Salivart Oral® Moisturizer are essentially the same. They use the same chemical components with the exception of a flavor and two preservatives used by Moi-Stir. Salivart uses neither a flavor nor preservatives. The only other difference between the two products is the method of dispensing. Moi-Stir uses a pump mechanism and Salivart uses an aerosol mechanism. Therefore, the products are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Denise E. Spellman
Director, QA & Regulatory Affairs (Official Correspondent)
Gebauer Company
9410 St. Catherine Avenue
Cleveland, Ohio 44104

Re: K981693
Trade Name: Salivart® Oral Moisturizer Model Number 03866-009-75 Saliva
Regulatory Class: Unclassified
Product Code: LFD
Dated: May 12, 1998
Received: May 13, 1998

Dear Ms. Spellman

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

S. Dutman for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981693

Device Name: Salivart® Oral Moisturizer

Indications For Use:

An oral moisturizer which temporarily relieves the discomfort of dry mouth (xerostomia) and dry throat naturally. Salivart may be used to replace human saliva, when the amount of saliva normally secreted has been reduced. Salivart lubricates the mouth and throat to soothe discomfort and assist in speaking and swallowing. Salivart relieves dry mouth caused by certain medications, therapeutic treatments, diseases, normal aging and emotional factors.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981693