K101346

JAN 27 2011

GC AMERICA INC.
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Section 6 – 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter Information:

GC AMERICA INC.
3737 W. 127th Street
Alsip, IL 60803

Contact Person: Mark Heiss, D.D.S.
Phone: (708) 897-4042
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Date Prepared: May 7, 2010

2. Device Name:

Proprietary Name: GC Oral Moisturizing Gel
Classification Name: Saliva, Artificial
Device Classification: Unclassified
Produce Code: LFD

3. Predicate Devices:

Company	Device	K Number
BioXtra Moisturizing Gel	Bio-X Healthcare S.A.	K072306
Oral Balance Liquid/Gel	Lacled, inc.	K061331

4. Description of Device:

GC Oral Moisturizing Gel contains polyglycerol (diglycerol) which, with other ingredients in the product, temporarily substitute the feel of natural saliva to moisturize, lubricate, and refresh the mouth. GC Oral Moisturizing Gel comes in five flavors: fruit salad, lemon, mint, orange and raspberry. GC Oral Moisturizing Gel is sugar free and alcohol free.

GC Oral Moisturizing Gel is substantially equivalent to BioXtra Moisturizing Gel and Oral Balance Liquid/Gel in its intended use. Both devices are artificial saliva agent designed for relief from dry mouth symptoms.

GC Oral Moisturizing Gel is designed to provide comfort for people suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

5. Indications for Use:

RX:

GC Oral Moisturizing Gel is designed to provide comfort for individuals suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

OTC:

GC Oral Moisturizing Gel is indicated for the relief of dry mouth symptoms, to provide a protective coating inside the mouth, and help to control bad breath.

6. Technological characteristics:

GC Oral Moisturizing Gel contains polyglycerol (diglycerol) which, with other ingredients in the product, temporarily substitute the feel of natural saliva to moisturize, lubricate, and refresh the mouth.

This mode of action of the applicant devices is substantially equivalent to that of the predicate devices, BioXtra Moisturizing Gel and Oral Balance Liquid/Gel.

7. Summary of Physical tests:

Summary of Performance Specification

	Consistency (mm)	pH
GC Oral Moisturizing Gel	32.5	7.2
BioXtra Moisturizing Gel	26.5	5.4
Oral Balance Gel	28.0	5.6

According to GC Corporation R & D test methods.

Moisture Desorption Assay

0.4g of products were placed on a weighing dish and weighed followed by incubation under the condition of humidity of 20% and a temperature of 37 degrees Celsius for 2 hours. A value obtained by dividing the weight change by the initial weight in terms of percentage was designated as moisture desorption degree. The results obtained are shown below.

GC Dry Mouth Gel: 6.9%
Biotene Oral Balance: 10.1%

8. Description of Safety and Substantial Equivalence:

The applicant device is substantially equivalent to the predicate devices in its intended use. Both devices are artificial saliva agent designed for relief from dry mouth symptoms.

All of the chemical components that constitute GC Oral Moisturizing Gel are previously used in the predicate devices which are legally marketed for the same indications and the same type of tissue contact. We believe that this fact well supports the compatibility of GC Oral Moisturizing Gel, and the safety of the applicant device is substantially equivalent to the predicate devices.

GC Oral Moisturizing gel is a wetting/moisturizing device.

Specifications and Substantial Equivalence Comparison

1. Device description and Intended Use

GC Oral Moisturizing Gel is designed to provide comfort for people suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

The applicant device, GC Oral Moisturizing Gel, is substantially equivalent to BioXtra Moisturizing Gel and Oral Balance Liquid/Gel in its intended use. Both devices are artificial saliva agent designed for relief from dry mouth symptoms.

2. Components and Mode of Action

GC Oral Moisturizing Gel contains polyglycerol (diglycerol) which, with other ingredients in the product, temporarily substitute the feel of natural saliva to moisturize, lubricate, and refresh the mouth.

This mode of action of the applicant devices is substantially equivalent to that of the predicate devices, BioXtra Moisturizing Gel and Oral Balance Liquid/Gel.

All of the chemical components that constitute GC Oral Moisturizing Gel are:

Chemical Formulation

GC Oral Moisturizing Gel

Component	Weight %	Predicate devices in prior use
Polyglycerol (Diglycerol)	60	
Pure Water	36	GC MI Paste Plus (K070854)
Sodium carboxymethylcellulose	2.5	GC MI Paste Plus (K070854)
Carrageenan*	1.5	
Sodium Citrate	<0.5	
Flavour	<0.5	
Ethyl p-hydroxybenzoate	<0.1	GC MI Paste Plus (K070854)

*Carrageenan is a thickening agent, CAS# 9000-07-1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Dr. Mark Heiss
Director, Academic & Regulatory Affairs
GC America, Incorporated
3737 West 127th Street
Alsip, Illinois 60803

JAN 27 2011

Re: K101346
Trade/Device Name: GC Oral Moisturizing Gel
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LFD
Dated: December 8, 2010
Received: December 9, 2010

Dear Dr. Heiss:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5 - Indications for Use Statement

Indications for Use

510(k) Number (if known): K101346

Device Name: GC Oral Moisturizing Gel

Indications for Use:

RX:

GC Oral Moisturizing Gel is designed to provide comfort for individuals suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth.

OTC:

GC Oral Moisturizing Gel is indicated for the relief of dry mouth symptoms, to provide a protective coating inside the mouth.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101346