OCT 2 1 2005

K051812

SECTION VI

PREMARKET NOTIFICATION SUMMARY

A. Submission Applicant and & Correspondent:

Name:	Laboratoires Carilene S.A. S.
Address:	7, rue de Chants des Oiseaux BP 52 78360 Montesson France Tel: 011-331-30-15-58-90
US Agent and Correspondent:	Emalee Murphy Kirkpatrick & Lockhart Nicholson Graham LLP 1800 Massachusetts Avenue, NW Washington, DC 20036 Telephone: 202-778-9428

B.

Name of Device:	TGO Spray®
Trade Name:	TGO Spray®
Common or Usual Name:	Saliva, Artificial
Classification Name:	Saliva, Artificial

C. Regulatory Information:

Product Code:	LFD
Classification:	Class II
Panel:	Dental

D. Devices to Which New Device is Substantially Equivalent:

Inpharma AB:	Caphasol cleared in K030802
Gebauer Company:	Salivart cleared in K981693
Sinclair Pharmaceuticals:	Salinum or Oraclair cleared in K024148

E. Device Description

TGO Spray® is an oral artificial saliva that contains oxygenated triglycerides from corn oil that have lubricating and moisturizing properties. The product is preserved, and supplied in a glass spray bottle containing 40 mL (1.35 fl.oz.). The spray pump delivers a metered dose of 0.100 mL per spray or approximately 400 sprays.

F. Indications for Use:

Rx: Under supervision of a healthcare professional, TGO™ Spray has been formulated for the relief of chronic and temporary xerostomia (dry mouth), which may be a result of disease such as Sjögren's Syndrome, oral inflammation, medication, chemo or radiotherapy, stress or aging. Symptoms include difficulties in swallowing, speech, and changes in taste. These symptoms may also be brought on by disease, stress, aging or medication.

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

Substantial Equivalence Comparison Chart

Product	TGO Spray®	Caphasol	Salivart	Salinum/Oraclair
Intended Uses	Symptomatic Treatment of xerostomia	Symptomatic Treatment of xerostomia	Symptomatic Treatment of xerostomia	Symptomatic Treatment of xerostomia
Method of Use	Ready to use spray	Mix parts A & B ampoules	Ready to use spray	Ready to use ampoules
Applications per Day	As needed	As needed	As needed	As needed
Disease State	Xerostomia	Xerostomia	Xerostomia	Xerostomia
Area of Use	Oral cavity	Oral cavity	Oral cavity	Oral cavity
Type of Product	Lipid Solution	Electrolyte Solution	Electrolyte Solution	Lipid Solution
Presentation	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile

H. Tests and Conclusions:

The TGO Spray® formulation has been shown in studies, including tests for acute oral toxicity, skin and mucous membrane irritation, skin sensitization, acute eye irritation, cytotoxicity, and human clinical studies, to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 1 2005

Laboratoires Carilene S.A.S.
C/O Ms. Emalee G. Murphy
Kirkpatrick & Lockhart Nicholson Graham, LLP
1800 Massachusetts Avenue, NW
WASHINGTON, DC 20036

Re: K051812
Trade/Device Name: TGO SPRAY
Regulation Number: NONE
Regulation Name: NONE
Regulatory Class: UNCLASSIFIED
Product Code: LFD
Dated: September 20, 2005
Received: September 21, 2005

Dear Ms. Murphy:

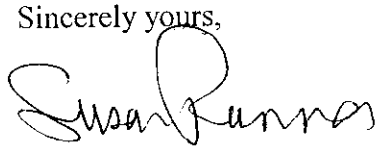
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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" (21CFR 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 Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION V

Indications for Use

510(k) Number (if known): K051812

Device Name: TGO Spray® Artificial Saliva

Indications for Use:

Rx:

Under the supervision of a healthcare professional, TGO Spray® is intended to provide relief from chronic and temporary xerostomia (dry mouth), which may be a result of disease such as Sjögren's Syndrome, oral inflammation, medication, chemo or radiotherapy, stress or aging. TGO Spray® relieves symptoms of dry mouth such as difficulties in swallowing, speech, and changes in taste.

Prescription Use ✓ (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 OF 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: K051812