K072306

510(k) SUMMARY

A. Submission Applicant Information and Correspondent:

Bio-X Healthcare S.A.,
21 Rue Herman Meganck
B-5032 Les Isnes
Belgium

NOV 1 5 2007

Registration Number: TBA

Contact:

Dr. Jean-Paul Perraudin PhD
Email: jp.perraudiin@biopole.com
Telephone : 011-32- 81- 723- 460

US Agent and Correspondent:

Emalee G. Murphy
Kirkpatrick & Lockhart Preston Gates Ellis LLP
1601 K Street, NW
Washington, DC 20006

Email: emalee.murphy@klgates.com
Telephone: (202) 778-9428 (Direct)
Fax: (202) 778-9100

B. Name of Device: BioXtra® Moisturizing Gel

Trade Name:	BioXtra® Moisturizing Gel
Common or Usual Name:	BioXtra® Moisturizing Gel
Classification Name:	Saliva, Artificial

C. Regulatory Information:

Product Code:	LFD
Classification:	Unclassified
Panel:	Dental

D. Devices to Which New Device is Substantially Equivalent:

Parnell Pharmaceuticals Inc.	Mouthkote Oral Moisturizer, cleared K062653
Laclede Inc.	Oralbalance Gel and Liquid, cleared in K061331
Gebauer Company:	Salivart Spray, cleared in K981693
Inpharma AB:	Caphasol cleared in K030802
Sinclair Pharmaceuticals	Salinum or Oraclair, cleared in K024148

E. Device Description:

BioXtra® Moisturizing Gel contains a patented formulation of milk proteins and salivary enzymes which, with other ingredients in the product, temporarily substitute the feel of natural saliva to moisturize, lubricate, and refresh the mouth. The product is supplied in a 1.4 fl. oz aluminum tube.

F. Intended Use:

Rx: Under the supervision of a healthcare professional, for 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. Relieves symptoms of dry mouth such as difficulties in swallowing, speech, and changes in taste and replaces missing saliva feel.

OTC: BioXtra® is indicated for the symptomatic relief from the effects of chronic or temporary xerostomia (dry mouth), mouth discomfort, mouth odors and other oral symptoms associated with dry mouth.

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

Substantial Equivalence Comparison Chart

Product Name	BioXtra®	Mouthkote	Oralbalance	Salivart	Caphosol	Salinum
Method of use	Ready to use gel	Ready to use liquid	Ready to use gel and liquid	Ready to use liquid spray	Mix Parts A & B ampoules	Ready to use liquid
# Applications per day	As needed	As needed	As needed	As needed	As needed	As needed
Claim	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia
Area of use	Oral cavity	Oral cavity	Oral cavity	Oral cavity	Oral cavity	Oral cavity
Disease state	Xerostomia	Xerostomia	Xerostomia	Xerostomia	Xerostomia	Xerostomia
Product Type	Solution	Solution	Solution	Solution	Solution	Solution
Presentation	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Rx/OTC	Rx/OTC	OTC	OTC	Rx	Rx	Rx/OTC

BioXtra® Moisturizing Gel is intended for the same indications and uses the same methods of use as predicate products.

H. Tests and Conclusions

BioXtra® Moisturizing Gel has been shown in laboratory and human tests 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

NOV 1 5 2007

Bio-X Healthcare S.A.
C/O Ms. Emalee G. Murphy
Attorney
Kirkpatrick & Lockhart Preston Gates Ellis L.L.P.
1601 K Street, NW
Washington, DC 20006

Re: K072306
Trade/Device Name: BioXtra® Moisturizing Gel
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LFD
Dated: October 31, 2007
Received: November 1, 2007

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.

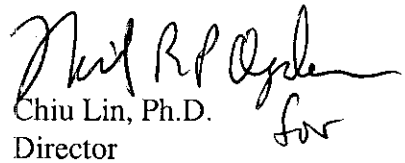
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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

K072306

SECTION V

Indications for Use

510(k) Number (if known): _____

Device Name: BioXtra® Moisturizing Gel

Indications for Use:

Rx:

Under the supervision of a healthcare professional, BioXtra® Moisturizing Gel is indicated for 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. Relieves symptoms of dry mouth such as difficulties in swallowing, speech, and changes in taste and replaces missing saliva feel.

OTC:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (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: K072306