

K091718

5. 510(k) Summary

A. From: Edward Kobus (Agent)
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Invado Pharmaceuticals
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SEP - 2 2009

Bartor Pharmacal (Owner)
70 High Street
Rye, NY 10580
Frank Bardani, RPh.

B. Trade Name: Neutrasal®

K091718

Common Name: Powder for Supersaturated Calcium Phosphate
Rinse

Classification Names: Saliva, Artificial

C. Regulatory Information:

Device Class: Unclassified

Product Code: LFD

D. Predicates: K030802, K991938

Caphosol®, Artificial Saliva

Product Code: LFD

E. Device Description:

Neutrasal® is a powder that when dissolved in normal tap water becomes a supersaturated calcium and phosphate rinse. Neutrasal® was designed in part to replace the normal ionic and pH balance in the oral cavity.

Neutrasal® also maintains moistness in the oral cavity. It relieves diffuse dryness and fissuring of the oral mucosa, as well as painful tongue conditions due to hyposalivation.

Neutrasal® facilitates chewing and speaking; loosens tough mucus; prevents mucous membranes from sticking together; and improves adherence of dentures.

Additionally, Neutrasal® can be used as an adjunct to standard oral care for relieving the discomfort associated with oral mucositis that may be caused by high dose chemotherapy or radiation. Relief of dryness of the oral mucosa in these conditions is associated with an amelioration of pain.

Neutrasal® is comprised of calcium chloride, sodium phosphate and sodium bicarbonate plus inactive ingredients. When Neutrasal® is dissolved in normal tap water, the water becomes supersaturated with both calcium and phosphate ions.

Syloid, an inactive ingredient in Neutrasal, is an amorphous silica that is recommended for free-flow and anti-caking for hydroscopic food powders, industrial powders and other applications (pharmaceuticals) where humidity must be kept to a minimum.

Product	Method of Use	Applications per day	Type of Product	Presentation
Neutrasal®	Dissolve Powder in Water	2-10 as directed by physician and indication	Electrolyte Solution	Non-Sterile

F. Indications for Use:

(OTC): Neutrasal® is indicated for the dryness of the mouth (hyposalivation, xerostomia)

(OTC): Neutrasal® is also indicated for dryness of the oral mucosa due to drugs such as antihistamines or atropine or other anticholinergic agents that suppress salivary secretion.

(OTC): Neutrasal® may be used as part of an oral hygiene program for patients with dry mouth. Neutrasal® also provides intensive hygiene of the oral cavity.

(Rx): Neutrasal® is also indicated as an adjunct to standard oral care in relieving the discomfort associated with oral mucositis that may be caused by radiation or high dose chemotherapy. Relief of dryness of the oral mucosa in these conditions is associated with amelioration of pain.

(Rx): Neutrasal® may be used for relief of dryness of the oral mucosa when hyposalivation results from the following: surgery, radiotherapy near the salivary glands, chemotherapy, infection or dysfunction of the salivary glands; fever; emotional factors such as fear or anxiety; obstruction of the salivary ducts; Sjögren's syndrome

G. Manufacturing

Neutrasal® will be manufactured according to product specifications and under the guidelines of current Good Manufacturing Practices (cGMP). Bartor Pharmacal, owner, is a cGMP-approved manufacturer.

Risk analysis has been performed to identify possible failure mode during manufacturing. Manufacturing controls have been developed and implemented to address the identified risks factors based on the criticality of failure mode. All established GMPs will assure that device manufactured at Bartor Pharmacal meets all established specifications prior to release and is safe and effective for its intended use.

H. Summary of Non-Clinical Testing: Performance

The Performance Testing of Neutrasal® included the assessment of the physical properties of Neutrasal® and its ability to achieve its intended use. Bench testing was completed by Scientech Laboratories, Inc., an FDA-approved analytical laboratory testing service as well internal testing done by Bartor Pharmacal. The following bench tests were performed:

- pH
- Dissolution Tests
- Activity Testing of Supersaturated State
- Content Testing of Active Ingredients

I. Biocompatibility testing

Neutrasal® is technologically identical to the 510(k)-approved product predicate with the exception that Neutrasal® is in a powder form to be reconstituted in water rather than being a pre-made oral solution.

J. GRAS Listing of Ingredients

The EAFUS list of substances contains ingredients added directly to food or medications that FDA has either approved as food additives or listed or affirmed as GRAS (generally recognized as safe). All ingredients contained in Neutrasal® are EAFUS approved food additives labeled as

GRAS. Only USP-approved chemicals, with validation, will be used during the manufacturing of Neutrasal®.

K. Other Information

Effervescence has proved its utility as an oral drug delivery system that offers advantages to other forms of drug delivery. Neutrasal® offers more portability because it is more easily transported than liquid medication because no water is added until the product is ready to use. Additionally, Neutrasal® offers improved penetration into the oral mucosa because of the effervescent formulation enhancement of sodium bicarbonate.

L. Substantial Equivalence Conclusion

The indications of use, technological properties, performance testing for Neutrasal® (Powder for supersaturated calcium phosphate rinse) are substantially equivalent to those of the predicate device Caphosol (supersaturated calcium phosphate rinse). They both share the same labeling and intended uses. Thus, Neutrasal® and Caphosol are substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Bartor Pharmacal Company, Incorporated
C/O Mr. Edward D. Kobus
Invado Pharmaceuticals
25 Ravenna Drive
Pomona, New York 10970

SEP - 2 2009

Re: K091718
Trade/Device Name: Neutrasal®
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LFD
Dated: June 19, 2009
Received: June 23, 2009

Dear Mr. Kobus:

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 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.

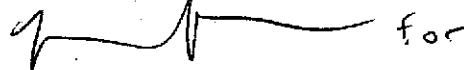
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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,

A handwritten signature in black ink, appearing to read "Susan Runner", followed by the word "for" in a smaller, simpler font.

Susan Runner, D.D.S., M.A.

Acting Director

Division of Anesthesiology, General Hospital,

Infusion Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K091718

Device Name: Neutrasal®

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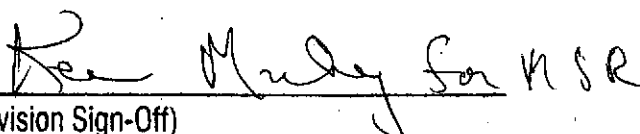
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Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use (21 CFR 801 Subpart C)

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



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091718