

K980132

JUN 26 1998

510(k) Summary

(a) **General Information**

(1) **Submitter Information:**

PhytaTek Laboratories, Inc.
210 Grant St. (Suite 1)
Pittsburgh, PA 15219
(412) 392-1533
(412) 391-8113 (fax)

Point of Contact: Mr. Mark G. Lombardo
Date Summary was prepared: 6 January 1998

(2) **Device Name:** phytacare™ Alginate Hydrogel Wound Dressing
Common Name: Hydrogel Wound Dressing

(3) **Legally Marketed Devices to which Substantial Equivalence is Claimed:**
phytacare™ Alginate Hydrogel Wound Dressing is substantially equivalent to one or more of the following legally marketed devices:

1. CarraGauze® - Carrasyn® Hydrogel Wound Dressing, Carrington Laboratories
2. Curasol™ Gel Wound Dressing, Healthpoint Medical
3. DermaGran™ Hydrophilic Wound Dressing, Derma Sciences
4. TransiGel™ Conformable Gel Dressing, Smith & Nephew United, Inc.
5. Biolex™ Impregnated Wound Dressing, C.R. Bard, Inc.
6. Saf-Gel®, Hydrating Dermal Wound Dressing with Alginate, ConvaTec

(4) **Description of Device:** phytacare™ Alginate Hydrogel Wound Dressings are highly conformable, sterile, primary wound dressings intended to provide a moist environment for the management of moderately exuding, partial to full thickness wounds.

There are 2 components of the phytacare™ Alginate Hydrogel Wound Dressing: a standard 12-ply cotton gauze pad and the phytacare™ Alginate Hydrogel. The primary function of the alginate component of the phytacare™ Alginate Hydrogel Wound Dressing is to absorb excess wound exudate, providing a moist wound environment to encourage

healing. The phytacare™ Alginate Hydrogel also contains common humectants and moisturizers, thickeners and stabilizers, anti-oxidants, preservatives, and a fragrance.

The dressing is packaged in a foil laminate pouch.

(5) **Intended Use of the Device:** phytacare™ Alginate Hydrogel Wound Dressing is an alginate hydrogel wound dressing that is indicated for the management of diabetic ulcers, foot ulcers, 1st and 2nd degree burns, pressure ulcers stages I-IV, cuts, and abrasions. This intended use is shared by the predicate devices.

(6) **Technological Characteristics of the Device; Comparison to the Predicate Device:** phytacare™ Alginate Hydrogel Wound Dressing is similar in function, composition, and intended use to the predicate devices, all gel-type wound dressings, as described in (a)(3) above. phytacare™ Alginate Hydrogel Wound Dressing also contains sodium alginate, whose primary function is to absorb excess wound exudate, providing a moist wound environment to encourage healing.

(b) **Performance Data**

(1) **Non-clinical tests:** Standard biocompatibility tests were performed on the phytacare™ Alginate Hydrogel to establish device safety. All the test and assay results were negative, which indicates that phytacare™ Alginate Hydrogel Wound Dressing can be expected to perform safely in clinical situations. The above tests and assays are typically performed for medical devices such as wound dressings.

End of 510(k) Summary.



JUN 26 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Phytatek Laboratories, Inc.
c/o King and Spalding
1730 Pennsylvania Avenue, N.W.
Washington, D.C. 20006-4706

Attention: Ms. Elizabeth S. Crockett

Re: K980132
Regulatory Class: Unclassified
Product Code: MGQ
Dated: April 23, 1998
Received: April 23, 1998

Dear Ms. Crockett:

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 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 (the Act). You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled for use on third degree burns.
2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.
3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.
4. This device may not be labeled as a treatment or a cure for any type of wound.

The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81). The general controls provisions of the Act include requirements for annual

Page Two - Ms. Elizabeth S. Crockett

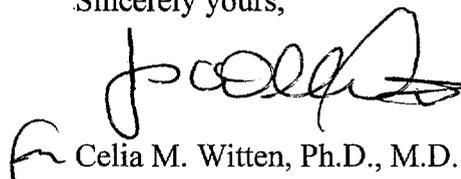
registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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 (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4595. 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" (21 CFR 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/dsmamain.html>.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General and

Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K980132

510(k) Number (if known): _____

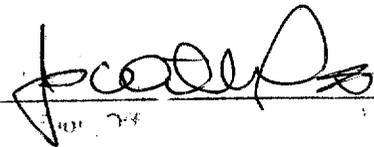
Device Name: phytacare™ Alginate Hydrogel Wound Dressing

Indications For Use:

For the management of: Diabetic Ulcers, Foot Ulcers, 1st and 2nd Degree Burns, Pressure Ulcers Stages I-IV, Cuts, and Abrasions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



RESTORATIVE DEVICES
510(k) NUMBER K980132

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)