510(K) SUMMARY

K982082

Trade Name: Derma-Wand

OCT 28 1998

Common Name: UV Radiator

Classification Name: Light, Ultraviolet Dermatological

National Biological Corporation declares through it's official correspondent Tracie Capozzio that to the best of it's knowledge, the proposed device family has the same intended use and similar technological characteristics as predicate devices (Birtcher Model 625 and R.A. Fischer CO UV-9 Therapy Lamp). It can be demonstrated that the proposed device is as safe and effective as the legally marketed devices and does not raise different questions regarding safety and effectiveness than the predicate device. This is based on the following areas of comparison between the proposed device and (referenced) predicate device:

Electrical Rating. The voltage, current, and power ratings and characteristics are comparable. High voltage breakdown and current leakage specifications meet current industry and medical device standards.

Digital Timer. The pre-1976 predicate device utilized an external manual timer which did not control exposure time. The proposed NBC and the previously cleared R.A. Fischer CO device utilizes an integral digital timer which is a current state of the art design used in other NBC medical devices to control UV lamp activation. Stated timer accuracy is +/- 3 seconds.

UV Lamps. The UV lamps, ballasts, and circuitry are identical to those used in current production devices. The predicate UV source and the proposed devices radiate energy levels and spectral responses which are comparable to each other and to devices currently in use for medical and commercial applications.

Operating Temperatures. The specified operating range (65 to 105 degrees F) is identical. There are no exposed, readily accessible high temperature areas which could pose a risk to the user or patient.

Key-switch safety. A key-operated power switch with removable key is standard on NBC products, to lock out timer/unit operation and prevent unauthorized device use. The predicate devices utilized an ON/OFF toggle switch.

Control and UV Wand. The grounded sheet metal control housing contains the timer and high voltage components. The UV fluorescent lamps and reflector assembly are enclosed in a light-weight plastic wand designed to allow the user to direct the UV radiation to selected wound areas. There is no physical body contact for treatment. Birtcher Model 625 device utilized an integral molded housing with a cold cathode quartz lamp, and did contact the body parts to be treated. The Fischer UV-9 utilized a molded housing with three plug-in germicidal bulbs.

Regulatory Requirements. The proposed devices will be manufactured and released within the established FDA Current Good Manufacturing Practices (CGMP) environment. The predicate device was distributed prior to 1976 and did not come under FDA/GMPs.

Product Safety. The Device Program Plan includes submission of the proposed finished devices to third-party evaluation by Electronic Testing Laboratories (ETL) and the Canadian Standards Association (CSA).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 1998

Ms. Tracie Capozzio
Director, RA and QA
National Biological Corporation
1532 Enterprise Pkwy.
Twinsburg, Ohio 44087

Re: K982082
Trade Name: Derma-Wand
Regulatory Class: II
Product Code: FTC
Dated: August 19, 1998
Received: August 24, 1998

Dear Ms. Capozzio:

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 (Act). 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 (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, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4659. 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,

for 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

Premarket 510(k) No. K982082

K982082

Device Name: Derma-Wand

INDICATIONS FOR USE

The National Biological Corporation Derma-Wand provides photo-therapeutic ultraviolet light. The UVB wand is indicated for dermatologic disorders such as psoriasis and vitiligo. While the UVC wand is indicated for dermatologic disorder in which bactericidal management is desired.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982082