

K973538

DEC 16 1997

510 (k) Summary
as required by 807.92(c)
for **N-TERFACE® Interpositional Surfacing Material**
Prepared July 10, 1997

Submitted by: Winfield Laboratories, Inc.
10488 Brockwood Road
Dallas, Texas 75238
214/553-8072

Contact Person: Gary W. Cummings
Executive Vice President

Device Trade Name: **N-TERFACE® Interpositional Surfacing Material.**

Common Name: Wound Contact Layer.

Classification: Wound contact layers have not been classified.

Predicate Device: **N-TERFACE® Interpositional Surfacing Material**
manufactured by Winfield Laboratories, Inc.,
10488 Brockwood Road, Dallas, TX 75238. (K820198).

Description of Device:

N-TERFACE® Interpositional Surfacing Material is an extruded, non-woven, high density polyethylene sheeting material with the following physical properties:
Weight, oz/yd²: 0.36 to 0.8, Thickness, Mils: 4.0 to 5.0,
Tensile, lbs/in.: roll direction 14 to 77, cross direction 1.5 to 4.5,
Air Permeability ft³/min/ft²: 545 to 1144.

Intended Use of Device:

N-TERFACE® Interpositional Surfacing Material is intended for use as the primary wound contact layer after laser skin resurfacing.

Substantial Equivalence to Predicate Device:

N-TERFACE Interpositional Surfacing Material indicated for use in laser skin resurfacing is physically identical to **N-TERFACE® Interpositional Surfacing Material** (K820198) indicated for use in the treatment of partial thickness burns. The wounds created in laser skin resurfacing are partial thickness burns. The material with this new explicit indication for a subset of the previously cleared use is therefore substantially equivalent to the device described in K820198.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 1997

Mr. Gary W. Cummings
Executive Vice President
Winfield Laboratories, Inc.
10488 Brockwood Road
Dallas, Texas 75238

Re: K973538
N-TERFACE™ Interpositional Surfacing Material
Regulatory Class: Unclassified
Product Code: MGP
Dated: September 18, 1997
Received: September 18, 1997

Dear Mr. Cummings:

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

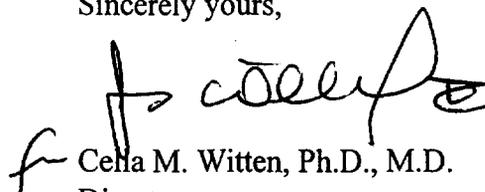
registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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

510(k) Number (if known): K973538

Device Name: N-TERFACE[®] Interpositional Surfacing Material

Indications For Use:

N-TERFACE[®] Interpositional Surfacing Material is indicated for use as a wound contact layer for partial thickness burns as a result of the procedure of laser skin resurfacing.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973538

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use