

6-1

K 961044

DR NOVIS SMITH & CO
1034 Laurel Oak Road
Voorhees, NJ 08043
800-668-4482
PA (215) 627-3200
Fax (215) 922-1211

JUL - 3 1997

510(k) SUMMARY

Prepared June 19, 1997

This 510(k) Summary for Noviguard Quick Dry has been prepared by Dr. Novis Smith who can be reached at the place of business noted in the letterhead and is the contact person.

Noviguard Quick Dry is a specially formulated general purpose disinfectant based on phenol and ortho phenyl phenol which are complexed reversibly with a olelyltrimethylenediamine (Adogen 572) and another basic polymer(PVP) to form a thin film which contains a high concentration of the phenolic disinfectant when dried. (This permits the use of low levels of phenol in the use solution to be about 0.5% yet when the very thin film dries the percentage of phenol is about 25% as the complex.) The phenol is retained and escapes as if in a slow release situation over week or more. the higher molecular weight components which also are disinfectants remain and maintain an effective disinfecting barrier. This whole formulation is dissolved in ethanol which permits the solution to dry within seconds for fast even application to surfaces. Ethanol does not attack most normally found surfaces in homes or hospitals.

We claim equivalence to Lysol which is based on just ortho-phenyl phenol. These are both products with at use concentrations of about 1% or less of active components. Both have been designed for the hospital and the home for primary disinfecting of exposed surfaces against a wide range of organisms. Noviguard Quick Dry is intended to be used as a general purpose disinfectant after cleanup has been accomplished or on surfaces nominally clean to maintain these surfaces in a disinfected state. This is achieved by using two phenols which act more rapidly and have a wider number of organisms which Noviguard would be effective against and in combination with the film forming polymer and olelyl trimethylenediamine. This unique combination permits the application of small amounts of disinfectant to surfaces and yet obtains maximum effectiveness since a rapid effective kill occurs and a longer lasting disinfecting action is maintained.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Novis Smith
President
Dr. Novis Smith & Company, Incorporated
701 Haddon Avenue
Collingswood, New Jersey 08108

JUL - 3 1997

Re: K961044
Trade Name: Noviguard Quick Dry
Regulatory Class: Unclassified
Product Code: LRJ
Dated: May 20, 1997
Received: May 21, 1997

Dear Dr. Smith:

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 (Pre-market 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

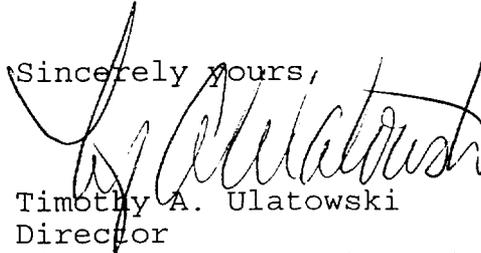
Page 2 - Mr. Smith

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) 594-4618. 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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3-5
STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K961044

Device Name: Noviguard Quick Dry

Indications For Use:

Noviguard is a general purpose disinfectant and is intended to be used on non-critical devices, dental and medical equipment, surfaces such as wheelchairs, dental chairs and medical beds in health care facilities.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chen S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K961044

Prescription Use

OR

Over-the-Counter Use