



NOV 6 1998

CENTRAL SOLUTIONS, INC.

K983585

3130 BRINKERHOFF RD.
P.O. BOX 15276
KANSAS CITY, KANSAS 66115
(913) 621-6542

Formulation • Development • Production

510(k) SUMMARY

SUBMITTER: Central Solutions, Inc.
3130 Brinkerhoff Road
P.O. Box 15276
Kansas City, KS 66115
Tel: (913) 621-6542

CONTACT PERSON: Paul Nobrega

DATE PREPARED: August 27, 1998

DEVICE TRADE / PROPRIETY NAME: Low pH Phenolic 256

DEVICE COMMON / USUAL NAME: General Purpose Disinfectant

CLASSIFICATION NAME: Unclassified

DISINFECTANT CATEGORY: Intermediate Level General Purpose Disinfectant

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

USE, FUNCTIONS, CONCEPTS, AND PERFORMANCE CHARACTERISTICS OF DEVICE:

Low pH Phenolic 256 is a liquid germicidal detergent formulated to clean, disinfect, and deodorize any washable, non-porous surface in one easy step. Low pH Phenolic 256 is recommended for use by hospitals, nursing homes, and other health care institutions that are dedicated to controlling cross-contamination in their establishments. Low pH Phenolic 256 is for use on any hard, inanimate surfaces such as door handles, medical bed surfaces, springs, wheelchairs, walls, floors, light switches, linen carts, stretcher wheels, toilet bowl surfaces, urinal surfaces, showers, bathtubs, bed frames, patient transfer lifts, patient scales, examination tables, dental chairs, medical lamps, stethoscopes, bedpans, blood donor chairs, and other hard, non-porous surfaces that need disinfection.

Efficacy tests have demonstrated that this product is an effective bactericide, fungicide, and virucide in the presence of organic soil (5% blood serum). When used as directed, Low pH Phenolic 256 demonstrates effective disinfectant efficacy against Mycobacterium tuberculosis (BCG) at 20°C, Staphylococcus aureus, Salmonella cholerasuis, and Pseudomonas aeruginosa. Low pH Phenolic 256 is fungicidal against the pathogenic fungi, Trichophyton mentagrophytes (Athlete's Foot Fungus) when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, or other clean, non-porous, hard surfaces commonly contacted by bare feet. This product, when used on environmental, inanimate, non-porous surfaces, exhibits effective virucidal activity against HIV-1 (associated with AIDS). HIV-1 (AIDS Virus) on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type-1 (HIV-1) (associated with AIDS).



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SCIENTIFIC PHYSICAL CHARACTERISTICS OF DEVICE:

Product Designation:	<i>Activated Synthetic Phenolic Base Disinfectant Cleaner</i>
Appearance (Concentrate):	<i>Clear light amber liquid</i>
Odor:	<i>Slight alcohol</i>
Percent of Phenolics:	<i>Concentrate: 14.735%</i>
pH (concentrate):	<i>2.25 ± 0.50</i>
pH (use-dilution):	<i>3.50 ± 0.50</i>
Specific Gravity (25°C):	<i>1.089 ± 0.01</i>
Flash Point:	<i>None</i>
Detergency:	<i>Excellent</i>
Phosphate Content:	<i>None</i>
Testing:	<i>A.O.A.C. in Hard Water up to 400 ppm in the presence of 5% organic soil load</i>



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 1998

Mr. Paul J. Nobrega
Registration Specialist
Dental Solutions, Incorporated
3130 Brinkerhoff Road
P.O. Box 15276
Kansas City, Kansas 66115

Re: K983585
Trade Name: Low pH Phenolic 256/Cen-pHene
Regulatory Class: Unclassified
Product Code: LRJ
Dated: August 27, 1998
Received: October 13, 1998

Dear Mr. Nobrega:

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 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). 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 requirements, 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

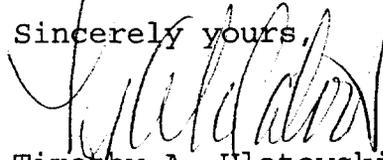
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4692. 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" (21CFR 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/dsma/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

510 (K) NUMBER (IF KNOWN) : K983585

DEVICE NAME : LOW PH PHENOLIC 258 / CEN-PHENE

INDICATIONS FOR USE :

Is a general purpose disinfectant

For use in health care settings for low and intermediate level disinfection of hard, non-porous, inanimate surfaces of wheelchairs, medical beds, patient transfer lifts, crutches, instrument trays, operating tables, stethoscopes, bedpans, blood donor chairs, dental chairs, medical lamps, whirlpool bathing units, and other medical devices that require low or intermediate level disinfection. This product may be used to pre-clean or decontaminate critical or non-critical medical devices prior to sterilization or high-level disinfection. The effectiveness of this product has been documented at a temperature of 68°F (20°C), with a ten minute contact time on the surface being treated.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1 - 2 -96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number _____