Food and Drug Administration 10903 New Hampshire Avenue Document Control Center - WO66-G609 Silver Spring, MD 20993-0002

WACOSA NACOSA NACOSA

Head of Department
Product Management & Regulatory Affairs
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Bandar Baru Calak Tinggi,
43900 Sepang,
Selangor

NACOSA NACOSA

A SERVICES - NO

Selangor Darul Ehsan

MALAYSIA 43900

Re: K133168

COSA NACOSA NACOSA Dermagrip Powder Free Blue Nitrile Patient Examination Gloves Non-Sterile
21 GFR 880.6250
tient Examination Gloves Trade/Device Name:

Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA med. July 1, 2014
Received: July 3, 2014

NACOSA NACOSA NACOSA NACOSA NACOSA NACOSA Product Code: LZA
Dated: July 1, 2014
Received: July 3, 2014

Dear Mr. Penner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the charges is substantially assessed and for the indicate the contract of the indicate the charges are substantially assessed and the charges are less than the charges are l referenced above and 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) that do not require approval of a premarket approval application (IMA). 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 adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling that the first limit has the first limit by

If your device is classified (see above) into either class II (Special Controls) or class III (PMA). Controls of the class III (PMA). Controls of the control of the controls of the control of the contro found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Enclosure

Please be advised that FDA's issuance of a subthat DA has made a determination theorem any Federal statutes and receivith all the Act's requirement 807) Significant 807 Signi of a substantial equivalence determination does not mean the Act has made a determation that your device complies with other requirements of the Act or any Federal statutes and regulations admirits and by other Federal agencies. You must comply with all the Act's equirements, including but not limited to: registration and listing (21 CFR Part 807), Sheling (21 CFR Part 8 11); medical device reporting (reporting of medical devicerelets, adverse events) (21 C.2. 803); good manufectung practice requirements as set forth in the quality systems (C.) regulation (21 CFR P. 1 320); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

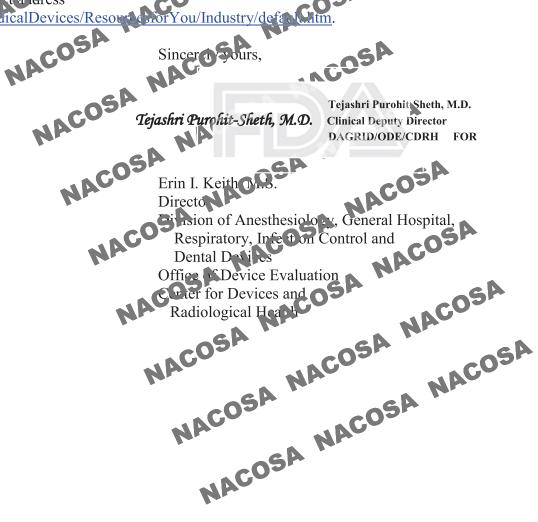
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division (SIndustry and Consumer Loucation at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet ad in each

http://www.ada.gov/MedicalDeviss-ResourcesforYou/Indisary/default.htm. Also, please note the regulation entitled, "Misbranding by reference to Dremarket notification" (21 CFR Part 807.97). For question regarding the reporting radverse events under the MDR regulation (21 CFR Part 803), Lease go to

http://www.fda.gov/MedicalDevical afety/ReportaProb efault.htm for the CDRH's Office of Surveillance and Biomedias/Division of Postmer et Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consume Education at its to<sup>11</sup>-tree number (800) 638 2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/ModicalDevices/Resource for You/Industry/defan



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration Food and Drug Administration

### Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

N	COSA PEPAR
	510(k) Number (if known)
	K133168

Device Name

Dermagrip Powder Free Blue Nitrile Patrent Examination Gloves Non-Sterile

Indications for Use (Describe)

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

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Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

## PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF

#### FOR FDA USE ONL'

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

# Sreekanth Guta

Digitally signed by Sreekanth Gutala - S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342,19200300.100.1.1=2000540490, cn=Sreekanth Gutala - S Date: 2014.08.07 13:21:07 -04'00' ACOSA

This section applies only to requirements of the Paperwork Reduction Act of 1995

## \*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\*

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