JUN 2 2 2004

K031368

CEPHAS MEDICAL
PRIVATE LIMITED

B-13, MEPZ - Special Economic Zone,
Chennai - 600 045. INDIA.
Tel.: 91-44-2262 1515 Fax : 91-44-2262 1616
E-mail : cephas@vsnl.net
Website : www.cephas.trade-india.com

DNV Accredited by the RvA
ISO 9001 : 2000 REGISTERED FIRM
DNV Certification B.V. THE NETHERLANDS

1.0 510K SUMMARY

1.0 APPLICANT :

NAME	: CEPHAS MEDICAL PRIVATE LIMITED
ADDRESS	: B – 13 MADRAS EXPORT PROCESSING ZONE TAMBARAM, CHENNAI – 600 045 INDIA
PHONE NO	: 91 – 44 – 2262 1515
FAX NO	: 91 – 44 –2262 1616
E MAIL	: cephas@vsnl.net
CONTACT PERSON	: Mr. THANGIAH IMMANUEL DIRECTOR
DEVICE TRADE NAME	: Powdered Latex Surgeon's Gloves
COMMON NAME	: Powdered Latex Surgeon's Gloves
Legally marketed device to which the company claiming equivalence	: Class I Surgeon's Gloves (Powdered) 79 KGO that meets all the requirements of ASTM D 3577 - 00
5 DESCRIPTION OF THE DEVICE	: Class I Surgeon's Gloves (Powdered) 79 KGO that meets all the requirements of ASTM D 3577- 00
6 Intended use of the device	: A powdered surgeon's glove is a disposable device made of natural rubber latex that bears powder to facilitate donning and it is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.
7 Technological Characteristics of device	: Nil
8 The Determination of Substantial Equivalence	: Nil
9 Assessment of Performance Data	: Nil
10 The Conclusions Drawn from the non Clinical & Clinical Test	: Nil
11 Any other information	: Nil

CEPHAS MEDICAL PVT. LTD.
B 13, MEPZ
CHENNAI
-600 045

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2004

Mr. Thangiah Immanuel
Director
Cephas Medical Private Limited
B-13 Madras Export Processing
Zone Tambaram
Chennai Tamil Nadu,
INDIA 600 045

Re: K031368
Trade/Device Name: Powdered Latex Surgeon's Gloves
Regulation Number: 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: May 15, 2004
Received: May 21, 2004

Dear Mr. Immanuel:

We have reviewed your Section 510(k) premarket notification of intent to market the device 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 (PMA). 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.

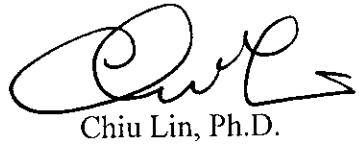
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510 (K) NUMBER :

DEVICE NAME : POWDERED LATEX SURGEON'S GLOVES

INDICATIONS FOR USE : A powdered surgeon's glove is a disposable device made of natural rubber latex that bears powder to facilitate donning and it is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.

Prescription Use .....
(Part 21 CFR 801 Sub Part D)

AND / OR

Over the Counter use .....
(21 CFR 801 Sub Part C)

Concurrence of CDRH Office of Device Evaluation (ODE)

Kevin Mulloy

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

510(k) Number: K 031368