

APR 21 2004

510(k) Submission – CHS-i1000

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: February 2, 2004

1. Company and Correspondent making the submission:

Name – Choong Wae Medical Corp.

Address – 698, Shindaebang-Dong, Dongjack-Gu, Seoul, Korea 156-010

Telephone – +82-2-840-6806

Fax – +82-2-841-1213

Contact – Mr. Myung Hak Cha

Internet – <http://www.cwm.co.kr>

2. Device :

Proprietary Name – CHS-i1000 Neonatal Incubator

Common Name – Infant Incubator

Classification Name – Incubator, Neonatal

3. Predicate Device :

Manufacturer : OHMEDA Medical

Model : 4000 CARE-PLUS

510(k) No. : K974349(Decision Date – February. 12. 1998)

4. Classifications Names & Citations :

21CFR 880.5400, FMZ, Incubator, Neonatal, Class2 Guidance document for the preparation of premarket notifications [510(k)'s] for Neonatal and Neonatal Transport Incubators.

5. Description :

The CHS-i1000 incubator provides a controlled temperature and humidity for infants. It is designed to minimize the effect of external heat loss on infants.

000029

The incubator is composed of 4 main elements namely, the hood, base, cabinet and controller. Together they measure W1000 x H1367 x D634mm. The foam based mattress that measures W690 x D370mm positions centrally within the confines of the hood. The mattress can also be raised at the head and foot end to a maximum incline of 12°. This is achieved by turning the handles that are located on each end of the base.

The hood is made of a clear acrylic to permit clear visibility of the baby yet provide isolation for the baby. The hood comprised of access ports gives access to the baby without compromising the thermal environment. Four of the access ports(two on the front and two on the rear) allow for regular access by the caregiver. The other two access ports are in the form of iris ports with are used primarily for ventilator tubes and monitoring cables to be channeled into the hood to the baby. Pulling the mattress towards the caregiver can enhance access even further.

6. Indication for use :

The CHS-i1000 Infant Incubator provides a controlled thermal environment for neonates who are unable to provide their own thermoregulation. They may be used for short periods of time to facilitate the neonate's transition from the uterus to the external environment. The CHS-i1000 Infant Incubators can be used in two operating modes, such as Air Control Mode and Skin Control Mode. The CHS-i1000 incubator is not for the transport of the patient.

The CHS-i1000 Infant Incubator has alarms to alert clinicians when certain patient or equipment conditions occur, such as a malfunction, or an excessive departure of the patient's temperature from the set value.

The CHS-i1000 Infant Incubator incorporates other features, such as humidification of the infant environment and tilting of the bed.

7. Comparison with predicate device :

Choong Wae Medical Corp., believes that the CHS-i1000 Infant Incubator is substantially equivalent to the 4000 CARE-PLUS of OHMEDA Medical.

8. Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1 and EN/IEC 60601-2-19 was performed, and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(1993), and Biocompatibility testing was conducted in accordance with standard ISO 10993-1. All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Choong Wae Medical Corp. concludes that CHS-i1000 is safe and effective and substantially equivalent to predicate devices as described herein.

10. Choong Wae Medical Corp. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END



APR 21 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Choongwae Medical Corporation
C/O Mr. Chan Yo Won
Responsible Third Party Official
Underwriters Laboratories, Incorporation
2600 N.W. Lake Road
Camas, Washington 98607-8542

Re: K040910
Trade/Device Name: CHS-i1000 Neonatal Incubator
Regulation Number: 880.5400
Regulation Name: Neonatal Incubator
Regulatory Class: II
Product Code: FMZ
Dated: March 9, 2004
Received: April 8, 2004

Dear Mr. Won:

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.

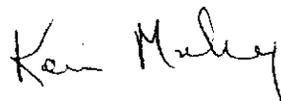
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

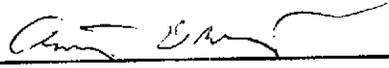


for Chiu Lin, Ph.D.

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



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

510(k) Number(if known):

510(k) Number: K040910

Device Name: CHS-i1000 Neonatal Incubator

Indications for Use:

The CHS-i1000 Infant Incubator provides a controlled thermal environment for neonates who are unable to provide their own thermoregulation. They may be used for short periods of time to facilitate the neonate's transition from the uterus to the external environment. The CHS-i1000 Infant Incubators can be used in two operating modes, such as Air Control Mode and Skin Control Mode. The CHS-i1000 incubator is not for the transport of the patient.

The CHS-i1000 Infant Incubator has alarms to alert clinicians when certain patient or equipment conditions occur, such as a malfunction, or an excessive departure of the patient's temperature from the set value.

The CHS-i1000 Infant Incubator incorporates other features, such as humidification of the infant environment and tilting of the bed.

Prescription Use AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation(ODE)