K964541

XIV. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

SEP 26 1997

Koike is submitting a 510(k) premarket notification for its oxygen conservation device, SANPO, which is intended for use in conjunction with oxygen supply systems to conserve and regulate oxygen supply and consumption. SANPO is intended for use by adults only, and not neo-natal or pediatric patients. Koike is claiming substantial equivalence to the oxygen conservation component of the PULSAIR® I and II liquid oxygen delivery systems manufactured by the $CRYO_2$ Corp. and cleared by the Food and Drug Administration under Section 510(k) on December 5, 1983 (K833994). The SANPO is substantially similar in its intended use, operational principles and product features to the oxygen conservation component of the PULSAIR I and II.

To support the substantial equivalence to the predicate products, the physical and technical characteristics of the SANPO have been compared to the oxygen conservation component of the PULSAIR I and II.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

Koike Medical Co.
c/o Mr. Stephen Paul Mahinka
Morgan, Lewis and Bockius LLP
1800 M Street, N.W.
Washington, DC 20036-5869

Re: K964541
SANPO I Oxygen Conserving Device
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II (two)
Product Code: 73 NFB

Dear Mr. Mahinka:

This letter corrects our substantially equivalent letter of September 26, 1997, regarding the SANPO I Oxygen Conserving Device. Our letter identified the product code as 73 BZD. This is in error; the correct product code is 73 NFB as indicated above.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K964541

STATEMENT OF INDICATIONS FOR USE

Device Name: SANPO

Indications for Use:

- For use by adults in conjunction with portable oxygen supply units to conserve and regulate oxygen supply and consumption. SANPO is not intended for use by neo-natal or pediatric patients.

Christy Foreman for AAC

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

- Prescription Use [X] OR Over-The-Counter Use __