APR 2 3 2002

Diasol Inc.

II. 510K SUMMARY IN ACCORDANCE WITH SMDA '90

SUBMITTER: DIASOL INC.
13212 RAYMER ST.
NORTH HOLLYWOOD, CA 91605
PHONE (818) 255-1800
FAX (818) 982-8539

CONTACT MONICA ABELES

DATE SUMMARY WAS PREPARED November 29, 2001

NAME OF DEVICE	DIASOL-BICARB
COMMON NAME	BICARBONATE FOR HEMODIALYSIS
CLASSIFICATION NAME	HEMODIALYSIS SYSTEMS AND ACCESSORIES CLASS II
PERFORMANCE STANDARD	NONE ESTABLISHED UNDER 514 OF FDA
PREDICATE DEVICE	RENOSOL K792213 and K781967 STERILYTE K971053

DEVICE DESCRIPTION:
Sodium Bicarbonate is part of the dialysate concentrate for hemodialysis. When mixed with AAMI standard water and Acid Concentrate, it creates a dialysate solution for use in renal dialysis therapy.
Diasol-BiCarb solution is in a ready to use form that is convenient for use in chronic care dialysis unit as well as acute care.
Sodium bicarbonate Hemodialysis grade, a white, water soluble powder is mixed with AAMI standard water and Sodium Chloride USP (for 36.83 proportioning) in adequate proportions to provide the bicarbonate part of the dialysate.
Diasol-BiCarb is packaged in a 1-gallon (3.785 liter) plastic container (HDPE) similar to the predicate.
The solution is non-sterile, non-pyrogenic. Finished product is gamma radiated.
Significant precautions have been taken to assure that the finished product does not promote bacterial growth.

AAMI microbiological standards are observed. LAL and microbiological cultures are performed on all batches using AAMI approved methods.
Our device has the same intended use as the predicate device ,we use the same grade of raw material and same type of packaging as our predicates

CONCLUSIONS:
Diasol-BiCarb andSterilyte and Renasol are both the bicarbonate components of the dialysate, with the same intended use and similar composition.
These similarities demonstrate substantial equivalence of Diasol-BiCarb to Renasol and Sterilyte.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2002

Ms. Monica Abeles
DIASOL, Inc.
13212 Raymer Street
NORTH HOLLYWOOD CA 91605

Re: K020230
Trade/Device Name: DIASOL-BiCarb
Liquid Sodium Bicarbonate
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 KPO
Dated: January 20, 2002
Received: January 23, 2002

Dear Ms. Abeles:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(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" (21 CFR 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,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Diasol Inc.

b. STATEMENT OF INTENDED USE

Device Name : Diasol-BiCarb
Indications for use: Diasol-BiCarb Solutions are indicated for use in acute and chronic hemodialysis and have to be used in conjunction with Diasol acid concentrate or any other commercially available concentrate in the correct proportioning and AAMI standard water as Dialysate solution for hemodialysis .For use in 3 stream dialysis machines calibrated for use with acid and bicarbonate concentrate.

Please do not write below this line

Concurrence of CDRH, Office of device evaluation (ODE)

Prescription Use ✓ **or** **Over-the-counter Use** _____
Per 21 CFR 801.109

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020230