OCT 10 1997

Attachment 9.

510(k) Summary
(as required by 21 CFR 807.92)

Submitted by: Dennis A. Ocwieja
Vice President
Regulatory Affairs and Quality Assurance
Clintec Nutrition Company
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Date Prepared: 03/08/96

Trade/Proprietary Name: Clintec Automix ® 3 + 3 / AS Compounder System

Common/Usual Name: Electromechanical Positive Displacement Fluid Compounding System

Classification Name: Compounding System with Integrated Computer Software

Classification: Class II in 21 CFR ξ 880.5440, Set, I.V., Fluid Transfer

Predicate Device: Clintec Automix ® 3 + 3 Compounder System

The Automix® 3 + 3 / AS Compounder System is an electromechanical positive displacement fluid compounding device that provides for the safe, fast, and accurate compounding of a wide variety of fluids via gravimetric weighing. It has the same operational and functional intended use and remains the same in all respects to the currently marketed system, except for the proposed modifications to incorporate a system to aid in the verification of source solution identity and placement.

The Positive Identification Solution Family Monitor, an equipment and software upgrade designed to aid in the verification of the identity of the source solutions being compounded, is a modification and upgrade to the compounding system currently marketed which is found substantially equivalent, for purposes of the Federal Food, Drug and Cosmetic Act only, to the Automix® 3+3 Compounder System under K894827, dated October 6, 1989.

Performance testing for the Clintec Automix ® 3 + 3 / AS Compounder System described in the submission demonstrates the functional acceptability of the proposed hardware and software modifications and enhancements.

The design changes are documented and their verification and validation procedures are described in the application.

000315

MAR 11 1996

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Ms. Marcia Marconi
Vice President Regulatory Affairs
Baxter Healthcare Corporation
Route 120 & Wilson Road
Roound Lake, Illinois 60073

OCT 10 1997

Re: K961008
Trade Name: Automix® 3+3/AS Compounder System
Regulatory Class: II
Product Code: LHI
Dated: September 26, 1997
Received: September 30, 1997

Dear Ms. Marconi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Susan Runner

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K961008

Device Name: Automix^{R} 3+3/AS Compounder System

Indications For Use:

This device is an electromechanical positive displacement fluid compounding device that provides for the compounding of fluids via gravimetric weighing.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rebecca Cincotta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K961008

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

10/09/97