

FEB 9 2000

SECTION 15: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR807.92

15.1 SUBMITTER INFORMATION

- a. Company Name: Tandem Medical, Inc.
- b. Company Address: 15910 Bernardo Center Dr.
- c. Company Phone: (858) 673-3900
Company Facsimile: (858) 673-3566
- d. Contact Person: Albert Misajon
Director, Regulatory Affairs
And Quality Assurance
- e. Date Summary Prepared: November 10, 1999

15.2 DEVICE IDENTIFICATION

- a. Trade/Proprietary Name: *AutoDose™ Infusion System - For Use with S.A.S.H.*
- b. Classification Name: Infusion Pump
21 CFR 880.5725

15.3 IDENTIFICATION OF PREDICATE DEVICES

<u>Company</u>	<u>Device</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
Tandem Medical Inc.	<i>AutoDose™ Infusion System</i>	K990889	June 3, 1999

15.4 DEVICE DESCRIPTION

The AutoDose Infusion System was designed to infuse Intravenous solutions of predetermined volumes in a predetermined order based on the configuration of the disposable bag. The system is capable of infusing Intravenous (IV) solutions of the following volumes in this order:

Chamber	Volume
1	≤10 mls.
2	≈25 – 120 mls.
3	≤10 mls.

4 ≤ 5 mls.

A Pharmacist may decide to use the AutoDose Infusion System with an AutoDose Bag filled with 0.9% Sodium Chloride Injection and Heparin Lock Flush Solutions, USP in conjunction with an Administration IV fluid. (Refer to figure 1). In this configuration, the AutoDose would deliver the IV fluids using the deliver regimen, commonly known as SASH' (Saline, Admistration, Saline, Heparin) and eliminate the need to use needles, syringes and access the IVAD (Intravenous Access Device) multiple times.

When the Pharmacist chooses to use the AutoDose Infusion system in this manner, an empty AutoDose Bag is filled with Saline and Heparin solutions drawn and prepared from the Pharmacy stores. After the prescription is filled with the main medication (i.e. Administration solution), the solutions are administered to the patient using the AutoDose Infusion System following the Directions for Use.

15.5 SUBSTANTIAL EQUIVALENCE

The AutoDose Infusion System used with 0.9% Sodium Chloride Injection and Heparin Lock Flush, USP solution is substantially equivalent to the original AutoDose Infusion System.

1. There is no change in the device Indications for Use, that is, the general use infusion of intravenous solutions.
2. There is no difference in the design of the unfilled AutoDose Bag and Restrictor Set. The design of the AutoDose Pump is unchanged. The materials used in the AutoDose Infusion System are unchanged.
3. The performance of the AutoDose Infusion System is the same in terms of infusion flow rates and pressures. The affect on the performance of the system due to the viscosity of either Sodium Chloride or Heparin solutions is insignificant. The compatibility and stability of the system with the two solutions have been verified.

15.6 INTENDED USE

The *AutoDose™ Infusion System* is intended for general use infusion of predetermined volumes of intravenous solutions.

15.7 PERFORMANCE

1. Device and Solution Compatibility and Stability
The *AutoDose™ Infusion System* was tested to verify that both 0.9% Sodium Chloride, Injection and Heparin Lock Flush Solutions, USP are both compatible and stable. The *AutoDose* Bag and *AutoDose* Restrictor Set were

filled with these solutions and tests were performed on the solutions per the applicable USP 24/NF 19 monographs. The results confirmed that the solutions meet all requirements over the storage periods and conditions.

2. Solution Infusion

The *AutoDose* System infuses IV fluids at consistent rates and pressures. Performance testing of the *AutoDose* Infusion System verified that the Saline and Heparin fluids would be consistently delivered in predetermined order and volumes, and generated infusion pressures no greater than 25 psi.

SAFETY

1. Biocompatibility

Safety testing performed on the *AutoDose* Bag and *AutoDose* Restrictor Set materials in fluid contact demonstrate they are biocompatible.

HAZARDS ANALYSIS

A Product Hazards Analysis was performed on the *AutoDose* Infusion System used with Sodium Chloride and Heparin solutions. The compatibility and stability of the solutions were tested and verified. No new or increased risk factors were identified.

S.A.S.H. is a widely used and accepted IV solution administration practice, especially in the intermittent administration of IV solutions using IVADs (Intravenous Access Devices). The solutions, Sodium Chloride and Heparin, proposed for use with the *AutoDose* Infusion System have previously been cleared for this purpose by FDA review. The performance testing of the *AutoDose* Infusion System verified safe consistent infusion times and pressures.

Therefore the use of the *AutoDose* Infusion System with 0.9% Sodium Chloride, Injection and Heparin Lock Flush Solutions, USP is deemed safe and effective based on the information presented.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 9 2000

Mr. Albert Misajon
Director, Regulatory Affairs and Quality Assurance
Tandem Medical, Incorporated
15910 Bernardo Center Drive
San Diego, California 92127

Re: K993832
Trade Name: AutoDose™ Infusion System
Regulatory Class: II
Product Code: MEB
Dated: November 120, 1999
Received: November 12, 1999

Dear Mr. Misajon:

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.

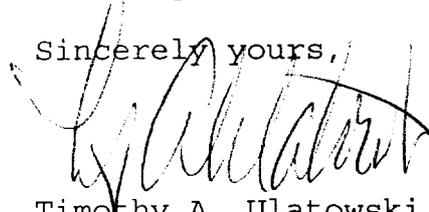
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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 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,



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

Enclosure

INDICATION FOR USE

510(k) Number: K993832

Device Name: *AutoDose™ Infusion System - For Use With S.A.S.H.*

Indications for Use: The AutoDose Infusion system is intended for sequential infusion of predetermined volumes of intravenous solutions including 0.9% Sodium Chloride Injection, (NaCl), and Heparin Lock Flush Solution, USP solutions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rafael Cuervo

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

510(k) Number K993832

Prescription Use

OR

Over-The-Counter Use