

AutoDose Infusion System
ORIGINAL PREMARKET 510(k) NOTIFICATION

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 CFR 807.92.

15.1 SUBMITTER INFORMATION

- a. Company Name: Tandem Medical, Inc.
- b. Company Address: 15190 Bernardo Center Drive
San Diego, CA 92127
- c. Company Phone: (619) 673-3900
Company Facsimile: (619) 673-3566
- d. Contact Person: Albert Misajon
Director, Regulatory Affairs
And Quality Assurance
- e. Date Summary Prepared: March 15, 1999

15.2. DEVICE IDENTIFICATION

- a. Trade/Proprietary Name: *AutoDose Infusion System*
- 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>
Douglas Medical Products	SoloPak® Sidekick Infusion Pump & Administration Set	K962663	10/4/96
I-Flow	Sidekick™ Infusion System	K915646	6/15/92

CONFIDENTIAL

15.4 DEVICE DESCRIPTION

The *AutoDose Infusion System* is a general use infusion system that is intended to infuse intravenous solutions of predetermined volumes in an order based on the *AutoDose Bag* configuration. It is intended that this system will infuse multiple intravenous solutions of predetermined volumes without user interaction. The system is comprised of the *AutoDose*, a mechanical roller device design in conjunction with the *AutoDose Bag*, a multiple chambered IV container, and the *AutoDose Bag Administration Set*. The single use multiple chambered IV container is designed to fit within the reusable *AutoDose* device with the end user pushing a start button once the *AutoDose Bag Administration Set* has been connected to the patient's indwelling access device. The *AutoDose Bag Administration Set* size will determine the system flow rate and will be offered in rates of 50 ml/hr, 100 ml/hr, and 200 ml/hr.

It is intended that the *AutoDose Bag* be provided empty and sterile to the end user. The *AutoDose Bag* can then be appropriately filled on the order of a physician by a pharmacy. The filling of the *AutoDose Bag* is performed using standard procedures, equipment and the *AutoDose Filling Fixture*. The *AutoDose Filling Fixture* is a tool developed to hold the *AutoDose Bag* for the pharmacist during the filling process. A clamp is automatically activated by the *AutoDose Filling Fixture* to securely close the bag after it has been filled.

The *AutoDose Infusion System* has been designed to simplify user interaction in the administration of multiple solutions safely with a reduction of a number of steps and a number of supplies typically used by healthcare providers.

The *AutoDose Bag* and the *AutoDose Bag Administration Set* will be sterilized per AAMI guidelines to a 10^{-6} sterility assurance level (SAL). Pyrogenicity will be LAL assessed per production lot in accordance with USP guidelines.

15.5 SUBSTANTIAL EQUIVALENCE

The Tandem *AutoDose Infusion System* is substantially equivalent to the SolaPak® Sidekick Infusion Pump and Administration Set and the I-Flow Sidekick™ in that each device is a mechanically spring driven infusion system intended for the infusion of general use intravenous solutions. The application of a constant pressure to the IV bag in conjunction with the fixed diameter and length of a restrictor in the administration tubing set achieve flow control in a similar manner. The flow rates (50, 100 and 200 ml/hr) for the *AutoDose Infusion System* are the same as those of the SoloPak® Sidekick Infusion Pump System and the I-Flow Sidekick™ Infusion System.

15.6 INTENDED USE

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

15.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the *AutoDose Infusion System* with the predicate device is provided within this submission. The *AutoDose Infusion System* and the predicate device are composed of a pressurization device, IV bag, and administration set. The *AutoDose Infusion System*, as well as the predicate is a mechanically spring driven pump system where flow is achieved by the application of a constant pressure to the IV bag in conjunction with the fixed diameter and length of a restrictor in the administration set. The *AutoDose* has the capability of infusing predetermined volumes in an order based on the *AutoDose Bag* configuration; whereas, the predicate has the capacity to either infuse two volumes in sequence or in parallel. Both systems utilize standard pharmacy procedures and equipment for filling of the dedicated IV Bag.

15.8 PERFORMANCE DATA

The *AutoDose Infusion System* was evaluated at the conclusion of the Final Design Phase to verify that the system met the product specifications. The *AutoDose*, *AutoDose Bag* and *AutoDose Administration Set* was tested and the results compared to the following product specifications: Average Flow Rate; Flow Rate Accuracy; Maximum Infusion Pressure and Residual Volumes. The results indicated that the *AutoDose Infusion System* performed to the requirements in the specifications. When compared to the Sidekick, the *AutoDose* is comparable in all common performance characteristics.

15.9 510(k) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the PreMarket Notification 510(k) Reviewer's Checklist is provided in this submission.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 3 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K990889
Trade Name: AutoDose Infusion System
Regulatory Class: II
Product Code: MEB
Dated: March 15, 1999
Received: March 17, 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.

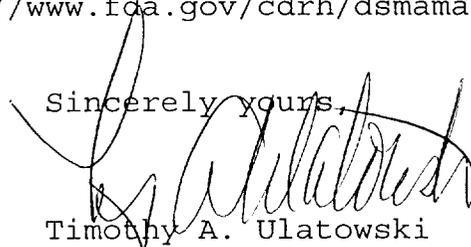
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Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws 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: To Be Assigned By FDA

Device Name: *AutoDose Infusion System*

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

510(k) Number 6990889