K 980165

APR 20 1998

Appendix F

510(k) Summary of Safety and Effectiveness

Date: January 5, 1998

Submitter:

Datrend Systems, Inc.
Unit #106 – 3070 Norland Ave.
Burnaby, BC V5B 3A6

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Contact Person:

Ron Evans,
VP Research and Development,
Quality Assurance Manager

Classification Name: Infusion Pump, accessory to (per 21 CFR section 880.5725)

Common Name: Infusion Pump Tester/Analyzer

Trade Name: Infutest 2000

Equivalency:

The Datrend Systems Infutest 2000 Infusion Pump Analyzer is substantially equivalent to the Bio-Tek IDA-2 Plus Infusion Device Analyzer (K961862) and the DNI Nevada 404A Infusion Pump Analyzer (K897096).

Description:

The Infutest 2000 Infusion Pump Analyzer is an instrument for measuring the volume of fluid delivered by an infusion pump. The instrument is based on an optically instrumented burette. Flow rates from 0.1 to 999.9 millilitres per hour can be derived from the incremental volume measurements in relation to the time of delivery. Infutest 2000 is a two channel system, which can be expanded to four channels by the addition of an accessory two channel sensor assembly called the Remote Sensor Module.

The Infutest 2000 is designed to accurately measure volumes and rates on a wide variety of infusion pump types, including syringe, linear and rotary peristaltic, cassette based, enteral and

patient controlled analgesia.

In addition to volume and flow rate, Infutest can measure the pressure developed by an infusion pump that is pumping into an occluded line. This feature is designed to measure the occlusion pressure alarm limits of the infusion pump.

Results of all tests performed can be printed to paper and/or sent to an external device using the serial communications port.

Intended Use:

The Infutest 2000 is intended to verify the correct operation of infusion pumps. Infutest 2000 is intended to be used by biomedical electronics technicians, manufacturers, third party service personnel, and others who may be charged with the responsibility of verifying the performance of infusion devices that operate in the flow rate range stated above.

Technological Characteristics:

The Infutest 2000 measurement system is based on an optically instrumented burette, placed horizontally in the instrument. The fluid flow is calculated by measuring the time required by the pump under test to deliver small increments of fluid volume, as low as 15 microlitres. The individual volume increments vary in size, depending on the fluid flow rate. The increments of volume are detected optically, by monitoring the position of a meniscus in the burette. The meniscus is created by injection of a bubble of air into the burette. This system allows continuous, uninterrupted fluid flow during a test. Flow rates in the range of 0.1 to 999.9 millilitres per hour can be measured accurately with this system.

Internal pressure transducers with a range of 0-50 psi measure the pressure developed by an infusion pump, which is pumping into an occluded line. A valve in the Infutest that is normally open during flow tests can be closed during pressure tests to create an occlusion.

The main unit of the Infutest 2000 system is capable of measuring flow rate, volume and pressures on two independently operating channels at the same time. The system can be expanded to four channels by the addition of a two channel remote sensor module. The main unit controls the remote sensor module, and results of tests are displayed on the main unit's LCD.

Operation of the instrument is controlled by four 'soft keys', which change function depending on the current display. The display is a 40 character by 8 line LCD, capable of graphical presentation. An external device, through the serial communications port, may also control the operation of the instrument by control codes that mimic the function of the direct keyboard input.

Infutest 2000 can perform any one of four basic tests on any of up to four test channels. The four

basic tests are: a) Single Rate, b) Dual Rate, c) PCA and d) Occlusion Pressure. The results from a test can be printer to paper using the Centronics parallel printer output port, or sent to an external storage device, such as a personal computer, using the serial communications port. Up to 9 test protocols, combining a timed rate test, a timed occlusion test and a formatted output, can be defined and saved by the user to increase productivity.

Inputs are provided to connect to an infusion pump's nurse call alarm output, and the operation of the alarm is checked as part of the occlusion pressure test.

Outputs are provided to activate the trigger input of a patient controlled analgesia pump during a PCA test.

Verification and Validation:

The Infutest 2000, the remote sensor module, the serial data transfer program and the graphics display program were extensively tested, verified and validated to be working per the input design and marketing specifications. The results of the testing indicates that the Infutest 2000 Infusion Pump Analyzer is substantially equivalent to the Bio-Tek IDA-2 Plus Infusion Device Analyzer (K961862) and the DNI Nevada 404A Infusion Pump Analyzer (K897096), and is safe and effective for its intended use.

The above information is submitted in accordance with the requirements of 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 20 1998

Mr. Ron Evans
President
Datrend Systems Incorporated
Unit 106 - 3070 Norland Avenue
Burnaby, B.C. V5B 3A6

Re: K980165
Trade Name: Infutest 2000 Infusion Device Analyzer
Regulatory Class: II
Product Code: MRZ
Dated: April 8, 1998
Received: April 10, 1998

Dear Mr. Evans:

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 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

510(k) Number (if known): K980165

Device Name: Infutest 2000, Infusion Device Analyzer

Indications For Use:

The Infutest 2000 Infusion Device Analyzer (Infutest) is intended to verify the correct operation of infusion pumps. Infutest is designed to be used by biomedical electronics technicians, third party service personnel, and others who may be charged with the responsibility of determining the functionality of an infusion pump.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K980165

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

(Optional Format 1-2-96)