

K973609

**BIO-TEK 510(k) Infusion Device Analyzer IDA-4 & IPT-MC APPENDIX G**

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U.S. FOOD & DRUG ADMINISTRATION

DEC 18 1997

CDER, HFD-514

ESSEX, VERMONT 05425

WWW SITE: <http://www.fda.gov>

**1- 510(k) SUMMARY**

**2- Contact Person:** Michael N. Sevigny Quality Assurance Manager  
802-655-4040 ext 336  
Establishment Registration Number: Bio-Tek 1217454 Filing  
Establishment will be marketing *IDA-4* versions  
2921581 DNI Nevada will be marketing  
*IPT-MC* versions  
Preparation date September 19, 1997



**3- Classification Name:** Pump, infusion, tester, MRZ, Class II  
**Common Name:** Infusion Pump Analyzer or Tester  
**Proprietary Name:** IDA-4 and IPT-MC

**4- Substantially Equivalent to:** The device family is equivalent to the legally marketed predicate devices: Bio-Tek Instruments, Inc. IDA-2Plus K961862 -predicate with the most similarity and some identical features;  
Dynatech Nevada, Model 404A, 510(k) # K897096.

*IDA-4 & IPT-MC* and the predicate Pulse Oximeter testers have an identical intended use and there are no new technological features or issues which would raise concern of safety and effectiveness.

**5 & 6- Description of Device and Intended Use:** The device family is intended for use as a infusion device tester or analyzer. It is not intended to be an infusion device calibrator.

The "*IDA-4 & IPT-MC*" incorporate one to four self reading calibrated micro-burettes (transducers) which measure the volume of fluid flowing from one to four infusion devices into the device. Flow rates from 1 to 1000 mL per hour can be administered independently in each channel. This device is designed to be used by manufacturers, BioMedical engineering departments in hospitals and third party service organizations to verify the accurate performance of infusion devices that operate in the range stated above. A wide range of infusion devices can be analyzed including: syringe, drop counting, peristaltic, and volumetric types. Non steady flow rate pumps can also be analyzed. The device is designed to operate using water or saline only  
The device can be used to determine flow rates, flow volume, average flow rate (with from -100 mmHg to +300 mmHg), average bolus volume with total delivery, occlusion pressure,

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### **7- Summary of technological characteristics of devices compared to predicate:**

The *IDA-4 & IPT-MC* are multi-channel devices capable of testing from 1 to 4 infusion pumps (or up to four outputs from 1 pump) simultaneously and independently. The predicate *IDA-2Plus* is a single channel device.

The *IDA-4 & IPT-MC* has a larger display (240 by 128 Supertwist LCD with backlight) capable of showing graphics or multiple lines of text at one time. The predicate *IDA-2Plus* has a single display line.

The *IDA-4 & IPT-MC* utilize 18 flow height "sensors" in the transducer thus giving better accuracy than the *IDA-2Plus* which had 4 "sensors". The transducer design is patented under *US Patent No. 4,938,072*

*IDA-4 & IPT-MC* and the predicate infusion pump testers/analyzers have a similar intended use and there are no new technological features or issues which would raise concern of safety and effectiveness.

### **8- Performance Testing: (Verification and Validation):**

The device was extensively verified and validated using a controlled written plan.

Each feature was determined to work correctly per the written specifications. Testing was successfully completed for: Flow Rate Accuracy, Volume Delivered Accuracy; Bolus delivery testing accuracy; Accuracy of Flow Rate under negative and positive backpressure; no cross talk between channels, and other features.

In summary the testing established that the *IDA-2Plus* meets its marketing specifications and is similar to the other devices as claimed in this submission.

**9- Clinical Testing:** Clinical testing was not required since the devices comprise test equipment, and are never in contact with a patient nor do they have any therapeutic or diagnostic patient function. As stated above they are not intended to be used as calibrators and should not be used for clinical "calls".

**10- Conclusions from testing:** The testing conducted to date and that will be conducted prior to release will support all product claims for intended use including accuracy and full feature operation.

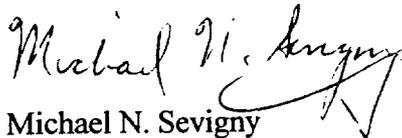
### **11. Other Information of Interest to FDA:**

**Potential System Hazards:** are classified as those which could affect the functionality of the system. The primary system function hazards which were reviewed and addressed were: a) To minimize the possibility of believable but incorrect results being displayed when measuring flow " and air-in-line detection monitor with error messages is utilized. b) Another potential hazard is from incorrect behavior of the device when the valve is blocked or partially blocked. If the value is outside of a range an error message is displayed and printed.

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**User Safety Considerations:** The device has been designed to meet the user safety requirements of IEC 1010-1 (1990)/ EN61010-1 "Safety requirements for electronic equipment for measurement, control and laboratory use. Part 1 General requirements". Features such as the sturdy drip proof plastic case were chosen with user safety in mind.

The above information is certified to be truthful and accurate to the best of my knowledge.

A handwritten signature in black ink, appearing to read "Michael N. Sevigny". The signature is written in a cursive style with a large, sweeping flourish at the end.

Michael N. Sevigny  
Quality Assurance Manager



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Michael N. Seigny  
Quality Assurance Manager  
Bio-Tek Instruments, Incorporated  
Highland Park, Box 998  
Winooski, Vermont 05404-0998

DEC 18 1997

Re: K973609  
Trade Name: IDA-4 and IPT-MC  
Regulatory Class: II  
Product Code: FRN  
Dated: September 19, 1997  
Received: September 22, 1997

Dear Mr. Seigny:

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 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 pre-market notification submission does not affect any obligation you might have under sections 531

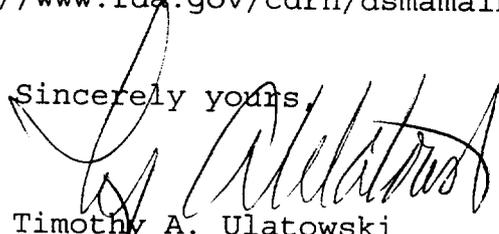
Page 2 - Mr. Sevigny

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,



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): \_\_\_\_\_

Device Name: \_\_\_\_\_ **IDA-4 & IPT-MC, Infusion Device Analyzer** \_\_\_\_\_

**Indications For Use:**

This **IDA-4 or IPT-MC** is designed to be used by manufacturers, BioMedical engineering departments in hospitals and third party service organizations to verify the accurate performance of infusion devices. It is not intended to be used as an infusion device calibrator. A wide range of infusion devices can be analyzed including: syringe, drop counting, peristaltic, and volumetric types. Steady and non-steady flow rate pumps can be analyzed. The device is designed to operate using water or saline only. It incorporates an RS232 serial port for computer control/data output and a Centronics type parallel printer port.

**Specifications:**

- One to four test channels each with independent operation.
- Average Flow Rate:
  - Range: 0.5 to 1000 mL/hr
  - Accuracy:  $\pm 1\%$  of reading  $\pm 1$  Least Significant Digit (LSD) for rates of 50 -100 mL/hr for delivery volumes over 20 mL. Otherwise  $\pm 2\%$  of reading  $\pm 1$  LSD after delivery of 5 mL. Specifications are with water at 15 to 25° C.
- Instantaneous flow rate is read from device display graph or PC screen:
- Delivered Volume:
  - Range 0 to 9999 mL
  - Accuracy:  $\pm 1\%$  of reading  $\pm 1$  Least Significant Digit (LSD) for rates of 50 -100 mL/hr for delivery volumes over 20 mL. Otherwise  $\pm 2\%$  of reading  $\pm 1$  LSD after delivery of 5 mL. Specifications are with water at 15 to 25° C.
- Flow and Accuracy Under Back Pressure:
  - Same accuracies as those listed above
  - Range -100 mmHg to +300 mmHg

(continued on page 2)

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\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

*Patricia Cuenca*  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number 1973409

Prescription Use   
(Per 21 CFR §801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

510(k) Number (if known): \_\_\_\_\_

Device Name: \_\_\_\_\_ **IDA-4 & IPT-MC, Infusion Device Analyzer** \_\_\_\_\_

**Indications For Use: Page 2**

• **Occlusion Pressure:**

Accuracy: 0 to 9 psi or 0-465 mmHg  $\pm$  5% of Reading  $\pm$  0.1 psi or 6 mmHg; 9 to 34 psi  
or 465 to 1762 mmHg  $\pm$  5% of Reading  $\pm$  0.2 psi or 12 mmHg  
Maximum Reading: 2326 mmHg; or 45 psi; or 310 kPa

• **Bar Code Wand and Gun capable, reads device under test ID for record storage purposes**

• **IDA-4 Graphics Software: Windows based, allows viewing of multiple graphs per screen, analyze review pump performance for: instantaneous flows; average flows; delivered volume; bolus volume.**