BIO-TEK® INSTRUMENTS, INC.
HIGHLAND PARK, BOX 998, WINOOSKI, VERMONT 05404-0998, U.S.A.

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510(k) SAFETY AND EFFECTIVENESS SUMMARY

Contact Person: Michael N. Sevigny Quality Assurance Manager 802-655-4040 ext 336

Classification Name: Pump infusion, **accessory to**, 80 FRN, 21 CFR §880.5725. Class 2

Common Name: Infusion Pump Analyzer or Tester

Proprietary Name: IDA-2 Plus

Establishment Registration Number: 1217454

Description of Device and Intended Use: **General:** The "IDA-2 PLUS" is a self reading calibrated burette which measures the volume of fluid flowing from an infusion device into the instrument. Flow rates from 1 to 1000 mL per hour can be administered. 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.

Operational modes: The IDA-2 Plus will offer two modes of operation; stand alone and computer control. The computer control mode will allow the user to operate the device from an external program. All possible tests available in the stand alone mode will be available in the computer control mode. The computer control mode allows for a graphical display of data, found to be useful in troubleshooting a faulty drive mechanism in the infusion device under test.

Reading Speed: The device can operate in the Steady Flow Mode, which will give a time to first reading of 6 minutes at 1 mL/hr and 25 seconds at rates above 100ml/hr. In the Non-Steady & High Accuracy Flow Mode it will depend on the time to deliver 1 mL of fluid.

Occlusion Pressure Range: The IDA-2 Plus features a pressure transducer that is operational in the range of 0 to 34.8 psi. It has the ability to display the pressure value in psi or mm Hg. A print out is also available.

Volume Measurement: This feature displays the volume delivered into the IDA-2 Plus.

Instantaneous/ Average Flow: This feature displays either the instantaneous or average flows through the device.

External communication links: The device uses a Centronics standard parallel interface that is Epson compatible. The printer can be set to print immediately after determining a rate or at intervals of 5 minutes or 1 hour. The serial RS232 port is used for computer control and is set at 2400 baud, using 8 databits, 1 stop bit and no parity.

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Data reduction software: "Graphics Capture Program " This feature of the device allows the user to acquire and continuously graph the flow rate, volume and occlusion pressure from a separate computer. Numerical values for average flow rate, instantaneous flow rate and derived volume can be displayed for any instant along the time axis. The user has the option to erase, print or save the acquired data for future review and statistical evaluation.

Similarity to other devices : The IDA-2 Plus is similar to other devices currently marketed in the US as infusion device testers by Datrends, Model Infutest 2000 no 510(k) # found, and Dynatech Nevada, Model 404A, 510(k) # K897096.

Verification and Validation: The IDA-2Plus and its associated Graphics Capture Program was extensively verified and validated to be working per the design and published specifications. 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.

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) Confusion between different IDA hardware and firmware versions. Error codes are given by the software. b) To minimize the possibility of believable but incorrect results being displayed in the "Non-Steady and Higher Accuracy (Flow) Mode" and air-in-line detection monitor with error messages is utilized. c) A third 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.

User Safety Considerations: The device has been designed to meet the user safety requirements of IEC 1010-1 (1990) "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.

Michael N. Sevigny
Quality Assurance Manager