

## 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

### I. Submitter

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### II. Contact

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### III. Device

Name of Device:	Instrument Manager V8.16.10
Classification Name:	Blood Establishment Computer Software and Accessories
Regulation:	21 CFR §864.9165
Regulatory Class:	Class II
Product Classification Code:	MMH

### IV. Predicate Device

Predicate Manufacturer:	Data Innovations LLC
Predicate Trade Name:	Instrument Manager V8.12
Predicate 510(k):	BK120051

No reference devices were used in this submission.

### V. Device Description

Instrument Manager is a stand-alone software package that provides connectivity between laboratory instruments and Laboratory Information Systems, aiding the flow of laboratory information, including test orders and results, specimen information, and patient information. Instrument Manager also provides data management functions that aid in the interpretation and management of laboratory results.

### VI. Indications for Use

Instrument Manager is a stand-alone software application for use in a blood establishment that provides connectivity between laboratory instruments and Laboratory Information Systems, aiding the flow of laboratory information, including test orders and results, specimen information, and patient information. Instrument Manager also provides data management functions that aid in the display and management of laboratory results. Instrument manager provides system checks to prevent Patient ID and Specimen ID mismatches and provides the capability for user enabled rules

which can be configured to hold results for verification before they can be released. Instrument Manager is a software package intended to be used by trained laboratory personnel as an aid in laboratory instrument interfacing and laboratory data management.

## VII. Comparison of Technological Characteristics with the Predicate Device

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

- **Indications for Use** – The predicate and subject device have equivalent indications for use. The subject device's indications for use includes additional description of the medical device functionality of the software, which is the same as the previously cleared versions.
- **Materials** – The predicate and subject device are both software products and do not have material concerns.
- **Design** – The predicate and subject device are equivalent designs with software updates and improvements made to the predicate device to become to subject device.
- **Energy Source** – The predicate and subject device have the same energy source, as they are powered by a computer operating system.
- **Performance Testing** – The predicate and subject device have been validated in the same way and the subject device meets all requirements and specifications.

## VIII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

### **Sterilization & Shelf-life Testing**

Not Applicable (Standalone Software)

### **Biocompatibility Testing**

Not Applicable (Standalone Software)

### **Electrical safety and electromagnetic compatibility (EMC)**

Not Applicable (Standalone Software)

### **Software Verification and Validation Testing**

The software has been developed in accordance with and verified and validated per IEC 62304:2006 Medical device software – Software life cycle processes.

### **Mechanical and acoustic Testing**

Not Applicable (Standalone Software)

### **Animal Study**

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

### **Clinical Studies**

Clinical testing was not required to demonstrate the safety and effectiveness of the Instrument Manager software. Instead, substantial equivalence is based upon benchtop performance testing.

## IX. Conclusions

The overall performance data in this submission supports that the Instrument Manager V8.16.10 is safe, effective, and substantially equivalent to the predicate device (previous version of the software), Instrument Manger V8.12.