

**For Immediate Release**

**Page 1 of 2**

## **FDA's MDDS Rule Applied to BEPAS and ADEPT Software Solutions**

### **MDDS designation allows for easier adoption and maintenance of data integration solutions**

**Grass Valley CA, February 25, 2015** – Applied Science, Inc. (ASI), a global technology solutions provider focused on unleashing the power of process automation and data, announced today that the U.S. Food and Drug Administration (FDA) has accepted ASI's application for Medical Device Data System (MDDS) status for both BEPAS (Blood Establishment Process Automation Solution) and its sister product ADEPT, patent pending (Automated Data Entry Process Technology ).

Blood centers and hospitals utilize a wide variety of devices in their daily operations. These devices produce data, which ultimately need to be entered into a system of record; a BECS (blood establishment computer system), in the case of blood centers, or an EHR (electronic health record) system in the case of hospitals. Traditional data integration software solutions require a direct interface with a medical device and as such, manipulate data in one form or another and thereby require a stringent FDA review and clearance known as a 510(k). The entire 510(k) submission and clearance process is both costly and exceedingly time consuming. Additionally, devices under this review process require evaluation of each change or modification to the software to determine if the change would require a subsequent 510(k) submission. Many companies are not willing to take on this effort. As a result, data is often marooned on devices and not integrated on either a timely, efficient or, in some cases an accurate basis because it is entered manually.

BEPAS and ADEPT provide a unique solution compared to traditional systems in that they automate the entry of data in a simple and straightforward manner. Because data is not manipulated in any way, using BEPAS or ADEPT, these systems fall under the FDA's definition of a MDDS and are exempt from FDA 510(k) review and clearance.

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**Page 2 of 2**

“These solutions provide a simple method for connecting existing devices with existing BECS and EHR systems and enabling the seamless automation of data entry,” said Jonathan Morgan, ASI CEO and President. “Hospitals in particular are now offered a solution that results in lowered costs, more accurate data entry, and greater operational visibility; all leading to improved patient safety.”

Timely information is important to hospitals as they work to improve their early warning systems and shorten notifications times to their Rapid Response Teams. EHR systems are designed to improve upon this process and produce better patient care results, but without the data from devices, often fall short.

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**About ASI**

Applied Science, Inc. (ASI), a global technology solutions provider focused on unleashing the power of process automation and data to provide simple and cost-effective solutions that optimize operating efficiency. ASI has a global footprint with customers and partners on four continents. ASI is based in Grass Valley, California. For more information, please visit [www.applied-science.com](http://www.applied-science.com)