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The ORACLE is a free newsletter of recent medical device regulatory & computer information that is of interest to designers, and device manufactures.

Delphi Consulting Group (DCG), provides medical device regulatory (FDA) release to market via the 510(k) and PMA pathways. DCG is Internet based to boost efficiency and reduce costs

FDA Warns Software Fix for Faulty Medical Device Not Evaluated

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Source: fda

*By **Fred Donovan***

May 24, 2019 - The FDA is warning that it has not evaluated a software fix for Beckman Coulter medical devices that is intended to flag inaccurate results from its blood test analyzers.

The company has told customers that a software update to the device may serve to alert laboratory personnel to any inaccurate results.

The agency said it is working with Beckman Coulter to determine if that software update alone can fix the faulty devices.

In the meantime, the FDA recommended that laboratory personnel use backup analyzers to confirm platelet results or perform manual platelet estimate/screening and follow the directions of a May 20 recall letter from the company before reporting platelet counts.

The devices affected by the recall are Beckman Coulter DxH 800, DxH 600, and DxH 900 hematology analyzers, which run blood tests to help providers diagnose diseases and conditions such as anemia, infections, blood clotting problems, blood cancers and immune system disorders.

In August 2018, Beckman Coulter first notified its customers that it had identified a problem that resulted in elevated platelet results occurring without error messages or alerts.

In April 2019, Beckman Counter provided additional information to the FDA, which asked the company to provide a second urgent medical device recall letter to customers, as well as send a letter with recommended actions to physicians likely to have patients affected by inaccurate results.

"Inaccurate platelet counts may create serious health risks for patients," said Tim Stenzel, MD, PhD, director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health.

"An inaccurate result may lead a provider to conclude a patient is suitable for surgery, when they may not be, to withhold platelet transfusion in patients who may need it, or to delay or miss the diagnosis of serious blood disorders," Stenzel said.

"Because this may cause serious injury, or even death, to a patient, we are urging health care professionals to be aware of the potential for inaccurate diagnostic results with these analyzers and to take appropriate actions including the use of alternative diagnostic testing or confirming analyzer results with manual scanning or estimate of platelets," he added. Coulter medical devices that is intended to flag inaccurate results from its blood test analyzers.

Software updates that add or remove claims as stated in the released 510(k) must be submitted to the FDA for release. The patient's lawyers will have a field day with this one.

How the FDA Uses Science to Speed Medical Device Innovation

The MDDT program streamlines the medical device development and review process.

FDA scientists in CDRH's Office of Science and Engineering Labs (OSEL) demonstrate a novel material that they have developed for assessing the safety of High Intensity Therapeutic Ultrasound (HITU) devices.

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By: Ed Margerrison, Ph.D., Director, Office of Science and Engineering Laboratories, and CAPT Hilda Scharen, Director, Medical Device Development Tools Program, Center for Devices and Radiological Health

New medical therapies have the ability to change and save lives, and advances in science and technology offer extraordinary opportunities to develop innovative medical products that can lead to better treatments and better care. But what happens when the accelerating rate of technological advances moves faster than the science for evaluating the benefits and risk of those products?

Responding to that challenge is an essential role played by the U.S. Food and Drug Administration (FDA) — helping to ensure that innovation in product development continues, so that patients can get groundbreaking medical products while at the same time ensuring patient safety and that harmful medical devices do not reach the market.

A Program for Advancing Safety and Innovation

One important action the FDA has taken to achieve this goal is the creation of the **Medical Device Development Tools (MDDT) program** at the Center for Devices and Radiological Health (CDRH). This program streamlines the medical device development and review process by advancing the development and use of scientifically validated and qualified methods, materials, and measurements for assessing how devices works.

Having a qualified tool means that product evaluation can be done more predictably and efficiently by providing innovators with the tools and techniques that FDA has found to be acceptable for their purposes. This can eliminate much of the risk and uncertainty developers often experience in product development.

Predictability also has important implications for the timeliness of the development process. It can help accelerate any phase of the development of a new therapy or diagnostic, from the rapid screening of prototypes to streamlining Ed Margerrison, Ph.D. clinical trial enrollment. In each case, it provides developers with greater confidence in the FDA's ability to review the data more accurately and quickly and avoiding unnecessary questions.

Before creation of the MDDT program, tools used by developers were evaluated on case-by-case basis — for each medical device submission. This added uncertainty, delay and inconsistency to the process, as well as additional costs and time to innovators and the FDA. That can now be largely averted, and FDA is looking to expand the program to as many areas as possible.

The use of a qualified tool also allows FDA regulators to concentrate on the most important aspects of the process and ensure that the end products are developed in a safe and timely manner. And, by qualifying tools for a specific use, the FDA facilitates their application for multiple medical device submissions and manufacturers, delivering greater efficiency and consistency to the community.

High Intensity Ultrasound Device Qualification Supports Greater Predictability and Reliability

One way to understand the importance of MDDTs is to consider **the recent qualification by the FDA of a tool for High Intensity Therapeutic Ultrasound (HITU) Devices**. Ultrasound has a long history as a medical device, with investigative products dating back to the 1940s. The ability of diagnostic ultrasounds to image in real-time, combined with its excellent safety record and modern-day portability, have led to its prominence worldwide.

Recently, the development and use of new technologies in this field, such as HITU as a minimally-invasive therapeutic tool, have been accelerating. Marketed devices now permit the treatment of certain cancers, uterine fibroids, and essential tremors, while clinical investigations into the treatment of many other brain disorders and various cancers are ongoing. These new uses represent promising advances for patients, but they also require precision to use them safely and effectively to achieve the desired effects.

In response to these developments, FDA scientists in CDRH's Office of Science and Engineering Labs (OSEL) have developed a material that can be used to mimic the behavior of tissue in a laboratory so that the effects of novel HITU devices and approaches can be assessed in a more reliable and predictable way. The mimic, known as a phantom, has recently been qualified as a MDDT. Device developers can now use this MDDT to help test the safety of their HITU device before exposing human patients in clinical studies. Understanding how their device performs early in development allows developers to improve a device's safety and make other modifications before moving to the next phase of development so those devices can be as safe as possible when they reach the market.

The FDA developed the new technology after observing a trend of increasing premarket submissions using HITU for a variety of treatments. FDA scientists focused on creating a standardized testing method for the developers who had been using their own individual formulations to develop phantoms or other methods of testing their devices.

The newly qualified tool can be used by the entire device development community. And, with this qualification, CDRH has now qualified MDDTs in every category of the program, which includes clinical outcome assessments, biomarker tests and nonclinical assessment methods. This means device developers can develop their products with increased confidence in the regulatory approach, and a faster and more transparent process.

Safety and effectiveness in new medical therapies are two sides of the same coin. It is the FDA's mission to improve both. As technology continues to advance, so will the medical devices have used by patients. By staying ahead of these changes and understanding and helping to shape the science that supports these advances, the FDA will continue to spur medical device safety and innovation, while ensuring that devices are safe and effective before they reach patients.

Windows 10 Will Let You Load a Custom Linux Kernel

Subtitled; Hell has not only frozen over but may be gone. Ever so slowly Microsoft is admitting Linux is the superior OS.

Larry Ewing

Microsoft is **adding a Linux kernel to Windows 10** to power the Windows Subsystem for Linux. But, guess what: You don't have to use Microsoft's Linux kernel. You can build your own custom Linux kernel for Windows to use.

This feature is part of the new version of WSL in Insider preview build 18945. This is a 20H1 build, which means it will likely be released in April 2020—it's unclear if this feature will make it to 19H2, expected for release in October 2019.

Microsoft had already added the Linux kernel, but now WSL 2 looks even more powerful than we originally thought. Now, you can do whatever you want with the Linux kernel, including adding kernel modules. You then specify the path to your kernel file in a .wslconfig file on your system and Windows will automatically load it whenever you launch a Linux system. You don't have to load a custom kernel—if you don't, Windows will just use the built-in one.

As Microsoft's Craig Loewen, program manager for the Windows Developer Platform, explains:
We provide a Linux kernel with WSL 2, and it's shipped within Windows. However, there may be a case where you want a specific kernel powering your WSL 2 distros, such as using a certain kernel module, etc. You can now use the kernel option in the .wslconfig file to specify a path to a kernel on your machine, and that kernel will be loaded into the WSL 2 VM when it's started. If no option is specified, you'll go back to using the Linux kernel provided with Windows as part of WSL 2. Don't you just love programmers speak.

There are more improvements to WSL, too. The entire .wslconfig global configuration file is new, and WSL users can now connect to Linux servers running on their system using localhost .

This latest insider preview build also features a redesigned Cortana experience, streamlined file search in File Explorer, and customizable text cursor indicator.

Microsoft Chris Hoffman

Delphi Consulting Group has had one or more computers running Linux since the early 1990's. Linux computers do not crash, are faster, and allow you decide totally what will be installed on the computer. Linux is just a operating system, no eye candy that cannot be changed. Try it and you will love it.

FDA Issues a Draft Guidance on Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment

Today, the U.S. Food and Drug Administration (FDA) issued the draft guidance: Testing and Re-Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment.
Read the Guidance at:
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/testing-and-labeling-medical-devices-safety-magnetic-resonance-mr-environment?utm_campaign=2019-08-01%20CDRH%20-%20Testing%20and%20Labeling%20Med%20Devices%20in%20MR%20Environment%20Draft%20Guidance&utm_medium=email&utm_source=Eloqua
Facts About the Guidance

The MR environment presents unique safety hazards for patients and other persons with medical devices near or inside an MR system. This draft guidance, when finalized, is intended to:
Provide recommendations on testing for assessing the safety and compatibility of medical devices in the Magnetic Resonance (MR) Environment. Identify test methods that address specific hazards and provide recommended format for Magnetic Resonance Imaging (MRI) Safety Information in medical device labeling.

This draft guidance will be open for public comments for 60 days at www.Regulations.gov under docket number FDA-2019-D-2837 .

In Houston Texas home of Delphi Consulting Group in August it really is summertime. August is our hottest month.

See you next month, stay safe.