What is Software as a Medical Device (SaMD)?

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There are three categories of medical device software. The first is Software in a Medical Device (SiMD). This category refers to products that are components of medical devices. The second is Software as an Accessory to a Medical Device. The third is Software as a Medical Device (SaMD). This category encompasses software that functions alone and not as part of hardware medical devices. It is important to note that software can be categorized as SaMD and still function with medical device hardware.

The U.S. Food and Drug Administration (FDA) regulates all of these categories of software. This software can diagnose, prevent and treat medical conditions. The platforms for this software include computers, smartphones, tablets and watches. Telehealth and traditional medical practitioners can use the software to monitor and treat patients.

Examples of SaMD:

- Mobile applications that utilize microphones to detect breathing and dependent medical issues are SaMD.
- Software that assists in the performance of medical imaging, related to the use of MRIs and X-Rays.
- Telemedicine provides the opportunity for patients to communicate on a remote basis with doctors through Zoom calls and other similar platforms.
- Diagnostic methods gather information collected from medical devices and use them to offer diagnoses of medical conditions.
- Disease management methods allow patients to monitor common ailments through reminders and support, including education.

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- However, collection of data that do not fulfill a medical function do not fall into the SaMD category; this includes communications between practitioners.

What are the Benefits of SaMD?

SaMD allow patients who do not have the benefit of nearby practitioners to receive advice and treatment without expensive devices. The technology can improve the quality of diagnoses and treatment because large amounts of information can be processed and acted upon quickly, even though the patient-doctor relationship is remote.

SaMD helps patients track their health, get immediate information and assist in their care through engagement with the doctor using SaMD.

All of this makes medical care less expensive, more efficient and more effective. It also ensures that people who might not otherwise seek out a doctor have access to one in their own homes.

What are the Negative Aspects of SaMD?

SaMD require extensive safety and efficacy testing and validation, as well as post-market monitoring, that pose time and cost issues for manufacturers and challenges for FDA, which is still working to manage the growing number of SaMD manufacturers seeking approval. These issues are more acute for smaller companies; many SaMD applicants are smaller companies.

The rapid pace of technological development is especially challenging. Devices are constantly updated, which often requires more interaction with an already overburdened FDA. This often results in delayed approvals and sometimes requires manufacturers to go back to the drawing board for certain elements of their products. Then there are the ubiquitous privacy issues that must be managed.

None of this suggests that smaller companies drop their plans for SaMD innovations, but they should be aware going in of the issues described above.

A number of best practices are recommended for developing and using Software as a Medical Device (SaMD). Some of these include:

- Conduct effective clinical trials, consulting with FDA before beginning trial work.
- Follow the recognized Standards and Guidance Documents facilitated by International Medical Device Regulators Forum (IMDRF), International Organization for Standardization (ISO), and FDA.
- Involve competent counsel and technical consultants, as well as a physician or physicians.
- Train your users.
- Stay abreast of regulations and trends in the industry.

What Does the Future Look Like?

The trend toward personalized and precision medicine, as well as telemedicine, will accelerate, and SaMD will be a key part of the process. The FDA's ability to keep up with the pace of change and provide prompt regulatory guidance and oversight will be critical.

SaMD products will work alongside and in conjunction with traditional medical device hardware. There will be increasing use of artificial intelligence and machine learning in the development of new SaMDs.

These trends will be followed by other new and exciting developments, and the result will be a drastic and welcome change in the delivery of health care for current and future generations.

Mark Mansour
202.454.2856
mansour@butzel.com

Debra Geroux
248.258.2603
geroux@butzel.com

Claudia Rast
734.213.3431
rast@butzel.com