WHITE PAPER | HEALTH SCIENCES

# 2019 – A YEAR IN REVIEW OF MEDICAL DEVICES

**As we reflect on 2019, NSF's Health Sciences regulatory consulting team highlights some key guidance documents, FDA programs, and notable device market authorizations in the United States.**

## NEW GUIDANCES/FDA PROGRAMS

### 510(k) Program Updates

Numerous 510(k)-related guidances were released in 2019, including the Special 510(k) Program[1] and Abbreviated 510(k) Program[2] including the circumstances under which these programs should be utilized. FDA also introduced the Safety and Performance-Based Pathway[3], which is an abbreviated 510(k) pathway for well-understood device types in which performance criteria can be utilized to demonstrate substantial equivalence.

### Humanitarian Device Exemption (HDE) Program

There have been a number of changes to the HDE program in the recent past, particularly with the passage of the 21st Century Cures Act. The FDA published a final guidance document[4] on the current review practices of the HDE program, to address commonly asked questions, including the differences between the HDE and the premarket approval (PMA) programs.

### Safer Technologies Program for Medical Devices

In September, FDA unveiled its new Safer Technologies Program for Medical Devices via a draft guidance document[5]. "STeP" creates a pathway similar to the Breakthrough Devices Program, but for devices (and combination products) that significantly improve the safety of treatments or diagnostics for diseases or conditions that are less serious. The intent is to continue to spur innovation and access for devices and IVDs in the U.S. market; the program's impact remains to be seen in 2020.

### Software-Related Guidances

FDA released a number of guidances on software and digital health at the end of September. The Agency finalized several guidances with updates that classified products previously under enforcement discretion as no longer being classified as medical devices, based on provisions of the 21st Century Cures Act:

- Policy for Device Software Functions and Mobile Medical Applications[6]
- General Wellness: Policy for Low Risk Devices[7]
- Off-The-Shelf Software Use in Medical Devices[8]
- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices[9]

Notably, FDA also released a new draft guidance[10] document for clinical decision support software, based on the extent of comments from the first draft release in 2017. This new draft guidance leveraged the 21st Century Cures Act and the International Medical Device Regulators Forum's (IMDRF's) risk-based classification

[1] The Special 510(k) Program | FDA
[2] The Abbreviated 510(k) Program | FDA
[3] Safety and Performance Based Pathway | FDA
[4] Final Guidance on Humanitarian Device Exemption (HDE) Program
[5] Draft Guidance on STeP
[6] Final Guidance on Policy for Device Software Functions and Mobile Medical Applications
[7] Final Guidance on General Wellness: Policy for Low Risk Devices
[8] Final Guidance on Off-The-Shelf Software Use in Medical Devices
[9] Final Guidance on Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices
[10] Draft Guidance on Clinical Decision Support Software

system for devices to create greater flexibility in the regulatory approach to these products. IMDRF also released a guidance on cybersecurity principles and approaches in October, as a step to better align international and U.S. regulatory approaches.

### Pilot Accreditation Scheme for Conformity Assessment Program (ASCA Pilot)[11]

FDA launched a pilot program, under which testing laboratories may be accredited by meeting criteria to assess conformance to certain FDA-recognized standards. Premarket submissions can be supported with testing performed by this ASCA-accredited testing laboratory if the testing was conducted per an eligible standard. A corresponding draft guidance[12] was also published to provide further clarify to potential participants. To participate, accreditation bodies and testing laboratories are required to demonstrate their qualifications per their respective roles to FDA.

### Guidance and Final Rule for Medical Device Submissions in Electronic Format

Finally, in the much-awaited publication of the final rule, the premarket regulations were amended to specify that submissions be provided in only one electronic copy, and without the need for paper copies. The associated final guidance, eCopy Program for Medical Device Submissions[13], was also revised to reflect these changes.

## OTHER REGULATORY DEVELOPMENTS

### FDA Advisory Panel on Silicone Breast Implants, Draft Labeling Guidance

CDRH convened an important meeting of its advisory committee in March 2019 to discuss breast implant associated-anaplastic large cell lymphoma (BIA-ALCL), and its linkage to textured implants. At this time, textured breast implants are still available on the U.S. market, but panelists agreed that more comprehensive data should be collected, and risks should be made clear to patients. FDA followed up with publication of a draft guidance[14] for labeling associated with breast implants in October 2019.

### Safety of Metals Used in Medical Devices

Since outlining a safety action plan for medical devices in 2018, and as part of a broader review of certain materials in implantable devices, FDA focused some of its efforts on the use of common metals and metal alloys in medical devices. In November 2019, FDA held an advisory panel meeting to discuss the safety of metals used in medical devices; there was a consensus that additional information regarding the immune responses to these products is needed, but methods for collecting data were not well clarified. Stay tuned for further FDA action on this hot topic.

### Ethylene Oxide Sterilization

Concerns were raised about the effects of ethylene oxide emissions on human health. Several facilities utilizing this sterilization method were closed, and some state agencies also determined that emission levels were unsafe. A shortage of devices was anticipated, and concerns were raised regarding the impact to public health should life-supporting and life-sustaining devices not be available. In addition to a public advisory committee meeting to discuss innovation in sterilization, FDA also announced a new Master File Pilot Program[15], which would allow review and implementation of sterilization changes in a more efficient manner.

### Exemptions From Premarket Notification for Class I and Class II Devices

At the end of 2019, FDA submitted a final order[16] that identified Class I and Class II devices that are now exempt from premarket notification requirements, with certain limitations. The list included devices such as clinical chemistry and toxicology test systems, clinical laboratory instruments, hematology and pathology devices, immunology and microbiology devices, ophthalmic devices and radiology devices. Glucose test systems were also included and have been the subject of active discussions since the release of this list.

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[11] Accreditation Scheme for Conformity Assessment (ASCA)

[12] Draft Guidance on The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

[13] Final Guidance on eCopy Program for Medical Device Submissions

[14] Draft Guidance on Breast Implants – Certain Labeling Recommendations to Improve Patient Communication

[15] Ethylene Oxide Sterilization for Medical Devices

[16] Final Order on Exemptions from Premarket Notification for Class I and Class II Devices

# NOTABLE REGULATORY DECISIONS FOR MEDICAL DEVICES

## BREAKTHROUGH DEVICES

Several notable devices were cleared/approved in 2019 after previously receiving breakthrough device designation:

- Optimizer® Smart system (Impulse Dynamics): Implant for chronic heart failure patients who cannot use a pacemaker or standard cardiac resynchronization therapy
- BAROSTIM NEO (CVRx, Inc.): System for improvement of symptoms in patients with advanced heart failure
- EXALT™ Model D single-use duodenoscope (Boston Scientific Corporation): The first fully disposable duodenoscope following FDA's safety communication[17] in August recommending that duodenoscope manufacturers and health care facilities transition to scopes with partially or fully disposable designs

## IN-VITRO DIAGNOSTICS

There were several notable firsts in the IVD space:

- OraQuick® Ebola Rapid Antigen Test (OraSure Technologies, Inc.): First rapid IVD for confirming Ebola infection
- Synovasure® Lateral Flow Test Kit (CD Diagnostics, Inc.): First diagnostic test to aid in detecting prosthetic joint infections
- ZIKV Detect 2.0 IgM Capture ELISA (InBios International, Inc.): First diagnostic for detecting Zika virus antibodies

## WEARABLE, TELEHEALTH AND MOBILE MEDICAL APP-BASED TECHNOLOGIES

In 2019, increasingly sophisticated mobile medical applications gained market clearance, including:

- Study Watch (Verily Life Sciences LLC): ECG smartwatch for adults with known or suspected heart conditions
- Loop System (Spry Health): Wearable for COPD monitoring
- Monarch® eTNS® System (NeuroSigma, Inc.): First medical device for treating ADHD

[17] FDA Safety Communication: The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety

For more information, contact **healthsciences@nsf.org** or visit **www.nsfhealthsciences.org**



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**NSF INTERNATIONAL | HEALTH SCIENCES**

789 N Dixboro Rd, Ann Arbor, MI 48105, USA

**T** +1 202 822 1850 | **E** healthsciences@nsf.org

**www.nsf.org** | **www.nsfhealthsciences.org** | Follow us on LinkedIn & Twitter

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