

Understanding FDA Guidance On Connected Medical Devices

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In the coming years, we expect to see an explosion in the number of interoperable medical devices. These are connected medical devices that have the ability to connect to different technologies and devices, even from other manufacturers. The U.S. Food and Drug Administration also recognizes the growing importance of these connected devices and issued final guidance on Sept. 6, 2017, relating to their safety.[1]

Interoperable medical devices can provide incredibly valuable data to health care providers and patients. Health information that may have taken several doctors' visits to gather could literally be at a patient's fingertips with a tap on their smartphone.

At the same time, these devices often have highly sensitive applications, such as pacemakers and blood pressure monitors, that give rise to unique safety risks. The guidance urges safety and transparency in developing and designing interoperable medical devices, and highlights information that manufacturers should include in premarket submissions and device labeling. This final guidance follows a draft guidance issued by the FDA in January 2016.

Background

The FDA guidance defines "interoperability" as the "ability of two or more products, technologies or systems to exchange information and to use the information that has been exchanged."

For example, a pulse oximeter — a device that monitors the amount of oxygen in the body — might send information to a computer system during a sleep study. The computer system could be receiving information from other devices simultaneously and integrating the data into a more convenient and functional format.

According to the guidance, manufacturers should implement appropriate functional, performance and interface requirements during product development to avoid exchanging inaccurate or untimely information that could cause patient injury. Common



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themes within the guidance include identifying anticipated users and potential misuses and conducting testing and thorough risk analysis of the medical devices.

The FDA noted on its website that it “has been collaborating with hospitals, health care providers, manufacturers, standards development organizations, and other interested parties to promote medical device interoperability.”[2] The agency has discussed the importance of interoperability in the past, providing examples to illustrate the need for safe and successful data exchange.[3]

For example, the FDA considered a scenario in which a patient in surgery is connected to a ventilator and a central monitoring station. If those devices are not interoperable, the FDA notes that the monitor may send a false alarm or fail to send a needed alarm. These errors could lead to serious injury.

A recent FDA blog post reiterates that the FDA’s first concern is safety and that the guidance is a step toward safer devices.[4] The guidance does not establish legally enforceable requirements, but it sheds light on the FDA’s current perspective on interoperable medical devices, and therefore informs the industry standard.

Ensuring compliance with that standard can help defend against potential product liability claims and claims that a manufacturer may not have lived up to its duty of care. Manufacturers should therefore take these guidelines into consideration when designing and developing connected medical devices and compiling premarket submissions.

Design Considerations

The FDA guidance lists six areas for consideration in designing interoperable medical devices: (1) the purpose of the electronic interface, (2) the anticipated users, (3) risk management, (4) verification and validation, (5) labeling considerations and (6) use of consensus standards.

Purpose of the Electronic Interface

The guidance encourages medical device manufacturers to clearly establish the purpose of the device’s electronic interfaces, and take that purpose into consideration when designing the device and developing relevant instructions.

The FDA suggests several elements for manufacturers to consider. For example, manufacturers should consider the types of devices it is meant to connect to, the type of data exchange taking place, the method of data transmission and the necessary timeliness and reliability of the information.

Anticipated Users

Companies should also identify anticipated users of the electronic interface, which the FDA notes will help in appropriately applying risk management strategies for developing instructions for use, contraindications, warnings and precautions.

Users could include biomedical engineers, IT professionals, patients and researchers, among others. Anticipated users should have enough information that they can use the electronic interface safely and effectively.

Risk Management Considerations

A variety of risk management factors for both intended and unintended access of the medical device should be considered by manufacturers.

The FDA lists several specific safety and security concerns to evaluate with electronic interfaces, including whether the interface reduces the safety or essential performance of the device, whether appropriate security features are included in the design and whether the device has the ability to handle corrupted data. Interoperable medical devices should be designed to mitigate risks associated with possible failures or malfunctions.

Verification and Validation Considerations

The FDA guidance further suggests that manufacturers conduct various verification and validation testing to ensure that the interactions on the electronic interface perform as intended and comply with the intended specifications.

This includes, for example, verifying that corrupted data can be detected and appropriately managed and allowing only authorized users to exchange information with the device.

Labeling Considerations

Medical device labeling should also provide information in a way that takes into account the anticipated users and the risk analysis.

The FDA further suggests that, even if a device is not subject to premarket submission, labeling recommendations for premarket submissions may be useful in ensuring clear labeling and in minimizing risk.

Use of Consensus Standards

Finally, the guidance encourages the use of recognized consensus standards, which can be found on the FDA Recognized Consensus Standards Database.[5] The FDA acknowledged that these standards may be used by manufacturers as well as other stakeholders such as health care delivery organizations.

As an alternative to a recognized consensus standard, manufacturers may opt to use their own design preferences. With either option, the FDA encourages manufacturers and health care organizations to implement interoperability in a standardized way, which may minimize misuse of medical devices and other potential problems.

Contents of Premarket Submissions

For interoperable medical devices that require a premarket submission, the FDA guidance sets forth additional considerations regarding the device description, risk analysis, verification and validation, and labeling.

Device Description

In a premarket submission, the device description should include a discussion of each “externally-facing electronic interface,” as well as the purpose and anticipated users of each interface.

Manufacturers should also specify if the interface is only meant to be used by the manufacturer or only with specific devices, and should include details regarding data exchange and usage.

Risk Analysis

With respect to risk analysis, the FDA notes that manufacturers should consider the risks associated with interoperability, as well as reasonably foreseeable misuses or potentially problematic events.

The guidance also recommends that manufacturers specify which mitigations they have implemented, and which may require implementation by other parties.

Verification and Validation

Manufacturers should include results of verification and validation testing for electronic interfaces as part of their premarket submission.

The specifics of the validation and the degree of documentation will vary depending on several factors, including the anticipated use of the device, associated risks and the purpose of the interface.

Labeling

The FDA guidance notes that labeling must comply with the requirements of 21 CFR parts 801 and 809, as appropriate, but includes recommendations intended to assist manufacturers in preparing labeling that satisfies those requirements. In particular, information that enables users to connect to the device in a specific manner should be included, as well as any limitations of the connection and any precautions, warnings or contraindications.

The guidance also includes a list of information that the FDA recommends including in the device labeling, depending on the purpose of the interface. This information includes, among other things, the specifications for each interface, recommended connections and recommended settings or configurations for the electronic interface.

Conclusion

The guidance acknowledges that the FDA and industry may need up to 60 days to implement these policies. If a premarket submission is received by the FDA within 60 days of the guidance publication and does not include information outlined in the guidance, staff does not intend to request this information during the review.

This guidance evidences the FDA's intent to maintain its focus on the safety and transparency of interoperable medical devices. As noted above, the guidance does not establish any new requirements, but does provide insight into the information the FDA expects to receive, and what it may emphasize in its review of interoperable medical devices.

Complying with the recommendations contained in the guidance will help satisfy the FDA that a manufacturer has accounted for appropriate risk and safety factors relevant to its connected device, and may help defend against product liability claims arising from the interoperable nature of the device.

Manufacturers of devices covered by the guidance should carefully consider these guidelines in their medical device design and development, as well as in their premarket submissions.

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[1]

<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM482649.pdf>.

[2] <https://www.fda.gov/MedicalDevices/DigitalHealth/ucm512245.htm>.

[3] <https://blogs.fda.gov/fdavoic/index.php/2013/08/improving-patient-care-by-making-sure-devices-work-well-together/>; <https://blogs.fda.gov/fdavoic/index.php/2016/02/building-a-case-for-medical-device-interoperability-fdas-call-to-action/>.

[4] <https://blogs.fda.gov/fdavoic/index.php/2017/09/interoperability-fdas-final-guidance-on-smart-safe-medical-device-interactions/>.

[5] <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.