EU Medical Device Regulations (MDR) Legacy Device Perspective

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A legacy medical device is a medical device that is already on the market and pre-dates relevant standards, directives, or regulations. In Europe, for example, the 1993 European Medical Device Directive allowed some devices exemption from meeting the new directive and allowed them to continue being marketed. Similarly, in the United States, the Food and Drug Administration's 510(k) allows devices that are substantially similar to a device marketed before 28 May 1976 to be marketed without going through the formal FDA approval process. (1)

The focus on legacy devices arises from the changes, over time, in the regulatory environment for development of medical devices and each generation of regulation brings with it new requirements that need to be met. The 1986 Tripartite Agreement (2) laid the groundwork for regulatory guidance of medical device safety evaluation leading to the development of the 1995 ISO 10993 (3) resulting in revisions over time. In recent times, the FDA has provided instruction for interpreting these guidelines using a risk management process and the MDR now brings more focus on risk management and post-market surveillance. In addition, technical standards for specific devices need to be regularly updated.

Previously, legacy devices have not been required to be followed up on once they have been put on the market. This means that devices can still be on the market for long periods without safety and efficacy follow-up as long as they have no serious incidents. Of subsequent concern, devices submitted as a 510(k) based on a predicate device, the original device may have been judged against a previous version of a regulation or standard. This means the original device may not be completely relevant to current standards and regulations resulting in subsequent devices possibly not complying with the full requirements for that type of product. Of particular concern are devices with a long history and each generation of the device is based on the previous resulting in a slow drift away from the safety and efficacy established for the first device. (1)

The new MDR addresses this concern as follows:
"Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of the regulation. Changes in device design or characteristics and changes in the harmonised standards or CS by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner." Article 10, part 9.

Therefore, the MDR specifies that any devices placed on the market must be kept up to date with any changes in standards or regulations, rather than just submitted and placed on the market with no follow up. Although every device available on the market must comply with the MDR by the date of application (26 May 2020), the impact on legacy devices has been clarified by the Medical Devices Coordination Group (MDCG) that issued a guidance document (on October 4th, 2019) on the validity of certificates issued under the (Active Implantable) Medical Devices Directive (AIMDD), following the Date of Application of the Medical Devices Regulation (EU) 2017/745 (MDR). This document specifies that legacy devices can be placed on the market until the certificate expires or until May 26, 2024, whichever comes first. (4)

References

1. Simons, Helen. The end of grandfathering? What the latest regulatory changes mean to you. Cambridge Design Partnership. Reviewed 01/20. https://www.cambridge-design.com/news-and-articles/blog/the-end-of-grandfathering

2. Tripartite Biocompatibility Guidance, G87-1, issued in 1986 by the US, Canada and the UK

3. International Standards Organization (ISO)

4. Emergo. European MDCG weighs in on legacy medical device certification issues and MDR. 10/2019. Reviewed 01/20. https://www.emergobyul.com/blog/2019/10/european-mdcg-weighs-legacy-medical-device-certification-issues-and-mdr