RA news round-up
CW 25 in 2023

Europe

Significant changes under Article 120 of the MDR

The guidance on significant changes under Article 120 of the MDR, which affect legacy devices, has been updated. This guidance is probably one of the most exciting guidance for most manufacturers, as it has the greatest practical relevance in daily business.

In terms of content, nothing has changed in the guidance (the MDR would also have to be revised for this), but some new examples have been included in the document. In the best case, this can clarify some questions about the application of the article.

United States

Voluntary use of the eSTAR tool possible

The FDA's electronic Submission Template and Resource is already available – now finally available for Pre-Submissions! These can now be submitted completely electronically.

In principle, the tool consists of a PDF template that guides you through the submission process and is intended to make it easier. Currently, the tool is still voluntary, but will become mandatory for all 510(k)s, de novo applications and Pre-Submissions from October. Excitingly, the FDA will probably not apply a Refuse to Accept to eSTAR submissions.

https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program?utm_medium=email&utm_source=govdelivery

Submission documents for Software functions

The guidance on the content of Premarket Submissions of software functions has been revised and is now finally available. The predecessor was published in 2005 and accordingly a lot has

happened: the document has grown from 23 to 45 pages. The entire structure has also been revised.

In the guidance, the interface to the risk management process is repeatedly emphasized; therefore, the level of information to be provided depends on the risk of the software for the user. The document does not give any instructions on the development of software, but you should have looked here in the early phase of product development in order to be able to meet the documentation requirements.

The guidance is available for download:

https://www.fda.gov/media/153781/download

Great Britain

Placing products on the market in the UK is still possible

So far, CE-marked medical devices could only be sold in the UK until the end of this month. Fortunately, the MHRA has reacted and adjusted the transition periods. For example, products marketed under the MDD (including active implants) can be placed on the market with our neighbours on the island by June 2028; IVDs (placed on the market under IVDD or IVDR) as well as MDR products still have time until June 2030.

The exact dates and the link to the implementation update can be found here:

https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#full-publication-update-history

Worldwide

IMDRF

As an addendum to the existing Guidelines and Practices for Medical Device Cybersecurity of 2020, the IMDRF has published two further guidances:

The first is aimed at manufacturers of legacy devices. This refers to products that are not necessarily old, but inadequately equipped against cyberattacks. The guidance contains practical tips on how to increase the cybersecurity of these devices:

https://www.imdrf.org/documents/principles-and-practices-cybersecurity-legacy-medical-devices

The second guidance introduces the principle of the Software Bill of Materials (SBOM). By listing all software components, security risks can be identified during development, but also after they have been placed on the market. Of course, this also applies to cybersecurity; the two documents therefore also refer to each other. The second guidance was also published on the IMDRF website:

https://www.imdrf.org/documents/principles-and-practices-software-bill-materials-medical-device-cybersecurity