RA news round-up
CW 42 of 2021

Europe

Postponement of the IVDR

It is not certain yet but already a bang for the buck: the European Commission has made a proposal for an extension of the transition periods of the IVDR for many risk classes. All in vitro diagnostics that have a valid IVDD certificate with an issue date before May 26, 2022 or those which would require the involvement of a Notified Body under IVDR, can benefit. Merely for manufacturers of medical devices that do not require the involvement of a Notified Body, the requirements will apply as before from the effective date of May 26, 2022.

The proposal is now under review; whether it will be adopted is still unclear.

Guidance on Classification of Medical Devices

The MDCG has published a helpful and practical guidance on the classification of medical devices. On 57 pages, the rules of the MDR are compared with those of the MDD, examples are given for the application of individual rules, and individual terms that might cause confusion are defined in more detail. We think the document is great. If you need further help, just contact us!

https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-24_en.pdf

International News

USA

Final Rule for De Novo Classification

In the U.S., a Final Rule has been published for the classification of novel medical devices going through a De Novo approval process. A similar text was already published in 2017 - but it never came into force due to requirements that were not compatible with the FDA's regulations and way of working.

The new document includes procedures and criteria for submitting a De Novo application. It also serves as a Q&A, as comments on an earlier draft are included, as well as responses that reflect the FDA's view on many issues. The document will

come effective on Jan. 03, 2022. Manufacturers seeking a De Novo request should look now to see what the regulations are. The document can be found here:

https://www.federalregister.gov/documents/2021/10/05/2021-21677/medical-device-de-novo-classification-process

Guidance on UDI assignment

Until December 13 of this year, a draft version of a guidance document on the UDI assignment to class 1 products is open for comment. In general, the document addresses so-called "consumer health products" that are often sold over the counter and whose UDI does not include a production identifier.

Although the document is primarily aimed at UDI issuing bodies, it is also advisable for manufacturers to read the guidance at least once.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-unique-device-identification-policy-regarding-global-unique-device-identification

Australia

Consent request with online form

In Australia, medical devices that do not meet the TGA's Essential Principles for safety and performance can still gain market access through a type of special approval. Consent from the TGA must be requested using a form. However, the paper-based system is now being replaced by an online form that can be found in the consultation hub. Soon, the form will move to the TGA Electronic Business Services, where even more functions will be available

https://www.tga.gov.au/form/essential-principles-consent-noncompliance

Classification of active Medical Devices

The TGA has published guidance on the classification of active medical devices. This now also includes software-based products. The document does not score points for its clarity, but for the helpful and detailed examples that have been added to each rule.

The rules in the document have not been arranged in ascending or descending order, but rather thematically.

https://www.tga.gov.au/sites/default/files/classification-of-active-medical-devices-including-software-based-medical-devices.pdf