RA news round-up
CW 40 of 2021

International News

USA

Template for 510(k) submission

Those seeking pre-market notification in the US previously probably used the electronic template provided by the eSubmitter software. Recently this has been replaced by the eSTAR template, which now enables a fully electronic submission.

This eSTAR template guides the user through the entire process, includes various databases, and asks helpful questions. You might think the future has arrived, but don't worry - the document still looks pretty "oldschool". Guidance on how to use the template has now been published in draft form. Comments can be made until the end of November this year.

By the way, the problem with the template is the following: apparently the full functionality only unfolds when using the paid versions of Adobe Acrobat.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions?utm_medium=email&utm_source=govdelivery

Australia

Repeal of Regulation 4.1

Very good news for European medical device manufacturers: Australian Regulation 4.1 has been repealed. This means that certain high-risk products no longer have to undergo a TGA conformity assessment procedure to be included in the Australian Register of Therapeutic Goods (ARTG).

Now, certificates of conformity from European Notified Bodies are sufficient for an application for inclusion in the ARTG. The change affects products containing medicines or materials of animal, microbial, recombinant or human origin and Class IV in vitro diagnostic devices, excluding both certificates issued under MDR and IVDR and those still issued under the old directives. Gaps between the European and Australian requirements are closed during an additional audit. Further information (also on possible costs) is presented on the website of the TGA:

https://www.tga.gov.au/conformity-assessment-certificates-changes-requirements-certain-medical-devices

Singapore

Cybersecurity vulnerabilities at Bluetooth-Interfaces

Again, bad news from Singapore for many medical device manufacturers: since last month, the security vulnerabilities Braktooth (Brak is Norwegian and means noise) are known, which affect the Bluetooth standards 3.0 to 5.2.

The chips of at least 10 major manufacturers are affected and medical devices could also be the target of attacks. An advisory from the Health Science Authority (HSA) in Singapore provides some information on the issue: it describes the potential extent of damage and gives tips on how to deal with the gaps. The document can be found here:

https://www.hsa.gov.sg/docs/default-source/announcements/safety-alerts/md-advisory_cybersecurity-vulnerabilties-(braktooth)-affecting-medical-devices-utilising-bluetooth-classic.pdf

India

Further lists for device classification

India has meanwhile become a regular at this point: quite a few more lists for the classification of individual product groups have been published.

As always, an explicit intended use is given for each device, with which comparisons can be made. They can be found - as always - on the homepage of the Central Drugs Standard Control Organization under Public Notices.

https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/Medical-Device-Diagnostics/