MDR, 510(k) Renew, Legacy Devices and SW Classification

How FDA And EU Are Coping With The Flood Of New Devices and Technologies

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- The FDA is renewing the 40 Y old 510(k) program

(1976: Medical Device Amendments to the FD&C Act).

It plans to retire legacy devices as predicates but does not subjects them to new demands.

- In the EU the MDR is posing stricter demands on all devices - clinical evaluation, PMS and vigilant compliance with current standards, including for legacy devices.

A grandfather or legacy device is a medical device that was already on the market and pre-dates an applicable standard, directive or regulation.

FDA: Since May 1976, manufacturers have been able to pursue an expedited clearanceif they could prove new products were substantially equivalent to those that were grandfathered when Congress established the 510(k) pathway.

PMS is required for **a)** implants longer than 1 Y, **b)** support/ sustain life outside a user facility, **c)** failure would be reasonably likely to have serious adverse health effects.
Otherwise: registration & Listing, GMP and adverse event reporting.

EU: Under the 1993 European MDD, legacy devices were exempt from meeting the new directive and allowed to continue being marketed. Under the MDR, legacy devices must comply, also to current standards.

In contrast to the FDA, the EU is subjecting legacy devices to the new demands – clinical evaluation, PMS, vigilance.

The perception gap

While the EU MDR is focusing on risk management and PMS for **ALL classes** and thus causing a huge problem for class I as well as legacy devices, the FDA aims to ''**Efficiently advance beneficial technology to patients, while solidifying FDA's gold standard for safety**'', thus is concerned with legacy devices that represent outdated technology unfit to be used for EQUIVALENCE today.

Comparing the FDA standpoint to the EU approach in the MDR raises profound question marks on the chances of harmonization.

FDA

Aiming to retire Legacy devices. The 510k path will not allow equivalence to decades old technology. In certain cases it is possible to use more than one predicate, and in addition Reference Devices.

EU

The MDR focus on risk management and PMS retires the MDD premise that, even though best practice has moved on, devices can still be on the market for long periods without going through any PMS scrutiny to ensure they are still safe and effective – as long as they have no serious incidents.

Clinical Evaluation – Burden on all classes

- Mandatory for initial CE-marking, conducted throughout the life cycle of a medical device thus must be continually updated – depending on PMS results, annually if significant risks are expected or 2-5 Y if none are expected (documented justification):

  - Class III: at least annually
  - Class IIb implants, drug administration: annually
  - Class IIb: every 2 years (PMS annually)
  - Class IIa: every 2-5 years (PMS every 2 years)
  - Class I: every 5 years (PMS when necessary)

- Significant effort on literature appraisal, separate for state of the art and product.
- Must Identify needs for PMS and PMCF (Post-Market Clinical Follow-up)

Clinical Evaluation – Burden on all classes

MEDDEV 2.7/1 Rev 4 and MDR:

- Clinical data are required for all classes, either by literature, or by studies – and more clinical investigations may be the result for devices that are not implants or high risk.

- Extensive literature appraisal.

- Assessment of risks

- Assessment of risk-benefit ratio

- Assessment of (not acceptable) side effects

- For class Iia, Iib, III, a Periodic Safety Update Report (PSUR) shall be prepared and incorporated in the CER.

- NB must prepare a CER Assessment Report

- The stricter demands on equivalence and changes in classification rules in MDR may cause further difficulties and unclear situations.

Limitations on exclusion of clinical studies

MDR Article 61 (5):

- Reliance on clinical data of equivalent device in order **not to perform** a **clinical investigation** may be done only if following conditions are fulfilled in addition to what is required in that paragraph:

- the two manufacturers have a contract in place that explicitly allows the manufacturer of the second device full access to the technical documentation on an ongoing basis, and

- the original clinical evaluation has been performed in compliance with the requirements of this Regulation,

- and the manufacturer of the second device provides clear evidence thereof to the notified body.

Equivalence – Stricter Requirements

- Equivalence must be shown in ONE medical device. Use of more than one ''predicate'' (partial equivalence from different products) is not acceptable. Article 61 section 3 1st indent:

''it is demonstrated that the device subject to clinical evaluation for the intended purpose is equivalent to the device to which the data relate...''

- Only CE-marked devices are allowed for equivalence.
- More detailed on development and production comparison (e.g. clinical/technical;/biological properties).
- In general, equivalence is only accepted for practically identical devices, data from "similar" devices may be used to define the state of the art (and for extended safety assessment)

FDA vs. EU - The Conceptual Gap

- In The EU the rigorous Clinical Evaluation requirements are considering as a 'continual improvement'.
- The FDA maintains it's rationale look on the world by trying to make sure in a reality of flood of new technologies, particularly in the digital healthcare, that it will be able to **continue allocate more resources to review higher risk devices** (see below).
- Apparently, in the EU this perspective has been somewhat lost.

- allowing the use of real world evidence,
- builds a national patient safety

And investing resources in developing:

- consensus criteria to serve for demonstration of SE in safety & performance,
- regulatory paradigm for digital health products,
- Pathways to enable patient access to new, innovative devices (breakthrough devices, quality in submission for expedite review)

SW Classification under the MDR

MDR Annex VIII - CLASSIFICATION RULES

Rule 11

''Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa…''