Regulation of companion diagnostics in the US and in Europe (IVDR)

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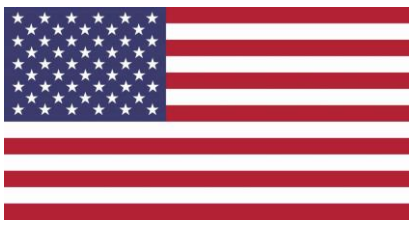


Definitions

A companion diagnostic is a medical device, often an in vitro device, which provides information that is essential for the safe and effective use of a corresponding drug or biological product. The test helps a health care professional determine whether a particular therapeutic product's benefits to patients will outweigh any potential serious side effects or risks.

'Companion diagnostic' means a device which is essential for the safe and effective use of a corresponding medicinal product to:
(a)identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or
(b)identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with

Classification

In the vast majority of cases, FDA classifies CDx as Class III Medical Devices under the rationale that the risk associated with the use of the CDx is similar to the risk associated with the drug that will or will not be administered on the basis of a CDx test.

In IVDR, CDxs are classified as class C IVDs under Rule 3

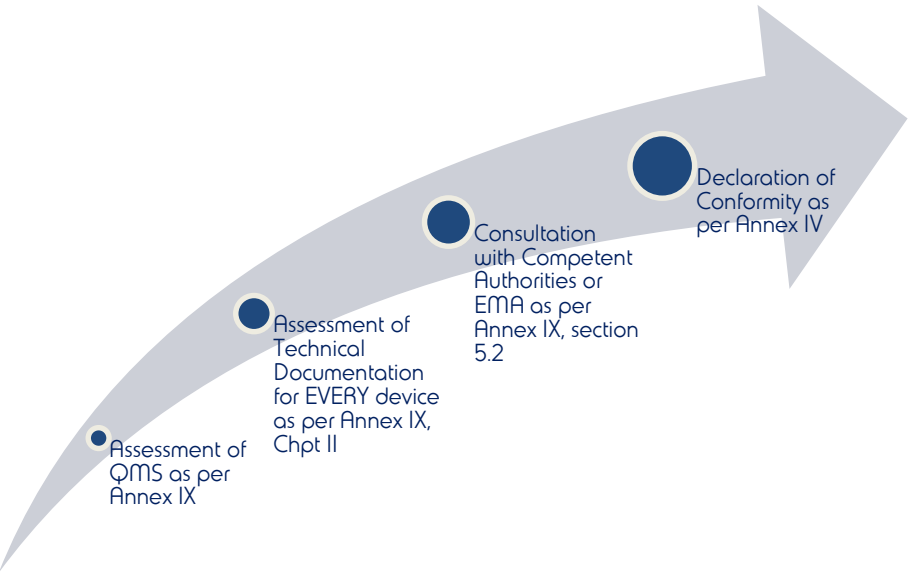
Regulatory pathway for approval

Class III Medical Devices require a premarketing approval (PMA) procedure acc. to section 515 of the FD&C Act.

Of the 44 currently FDA-approved CDxs (last update: Nov 2020), 40 have approved via the PMA procedure.
Two CDx tests (MRDx BCR-ABL Test & FerriScan) have been cleared by 510(k) and 2 by a Humanitarian Device Exemption (HDE) (i.e. device intended to be used for a disease that affects less than 8000 individuals in the US per year): KIT D816V Mutation Detection by PCR for Gleevec & PDGFRB FISH for Gleevec.

Note:
The IVD companion diagnostic device application will be reviewed and approved or cleared under the device authorities of the FD&C Act and relevant medical device regulations; the therapeutic product application will be reviewed and approved under section 505 of the FD&C Act (i.e., drug products) or section 351 of the Public Health Service Act (i.e., biological products) and relevant drug and biological product regulations, i.e. a PMA submission is reviewed by CDRH while a new drug application for a therapeutic is submitted and reviewed by CDER or thenCBER.

According to IVDR (Annex IX, section 5.2), the conformity assessment process for CDxs foresees a consultation procedure between a notified body and a medicine authority. This could take place between any of the national regulatory authorities in the EU or the EMA, depending on who is responsible for the authorization of the corresponding medicinal product. Under the current directives, the interaction between medicines authorities, EMA and notified bodies is limited to consultation procedures of devices that incorporate a medicinal substance.
For the CDx consultation procedure itself, the notified body will seek a scientific opinion from a medicine authority or EMA 'on the basis of the draft summary of safety and performance and the draft instructions for use' regarding the suitability of the device in relation to the medicinal product concerned. The timeframe for the consultation is 60 days with the possibility to extend once for another 60 days



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