Hardian Health

Innovate UK

Health Innovation Network South London

Module 10: Overseas regulation

Outline

Taking your medical device overseas

This talk will cover:

- US Food and Drug Administration
- Australia, Canada and others
- Medical Device Single Audit Program (MDSAP)

FDA is both authority and auditor

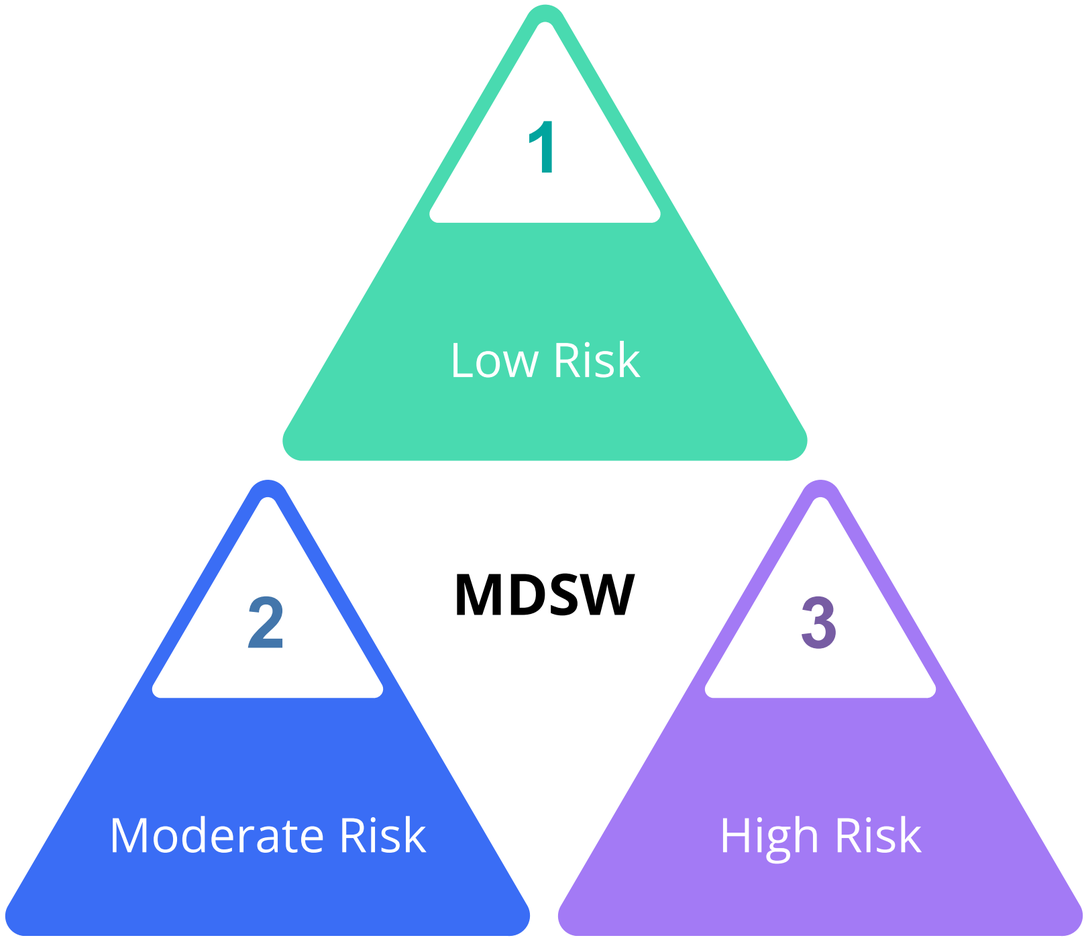
Vendors

FDA definition of Medical Device Software (MDSW)

> an instrument, apparatus, implement, **machine**, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them

> **intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man** or other animals

FDA risk classification



Four FDA pathways

Exempt

Simple registration only

510(k)

Based on a predicate device already cleared through de novo or PMA

De Novo

Low to moderate risk novel devices

PMA

High risk novel devices

Pre-submission (Q-sub)

Develop a “human” relationship with the FDA.

Remove some of the risk elements from your submission.

You get asked about things you don’t know and confirm things that you think you do know.

You can get **free** (non-binding) advice to help drive your development and regulatory strategy.

Opportunity to gain valuable feedback on your early documentation.

30–100 days depending on Q-sub type

FDA exempt Clinical Decision Support

- Does NOT acquire, process, or analyze medical images, signals, or patterns.
- Displays, analyzes, or prints medical information normally communicated between health care professionals
- Provides recommendations (information/options) to a HCP rather than provide a specific output or directive.
- Provides the basis of the recommendations so that the HCP does not rely primarily on any recommendations to make a decision.

510(k) - predicate equivalence

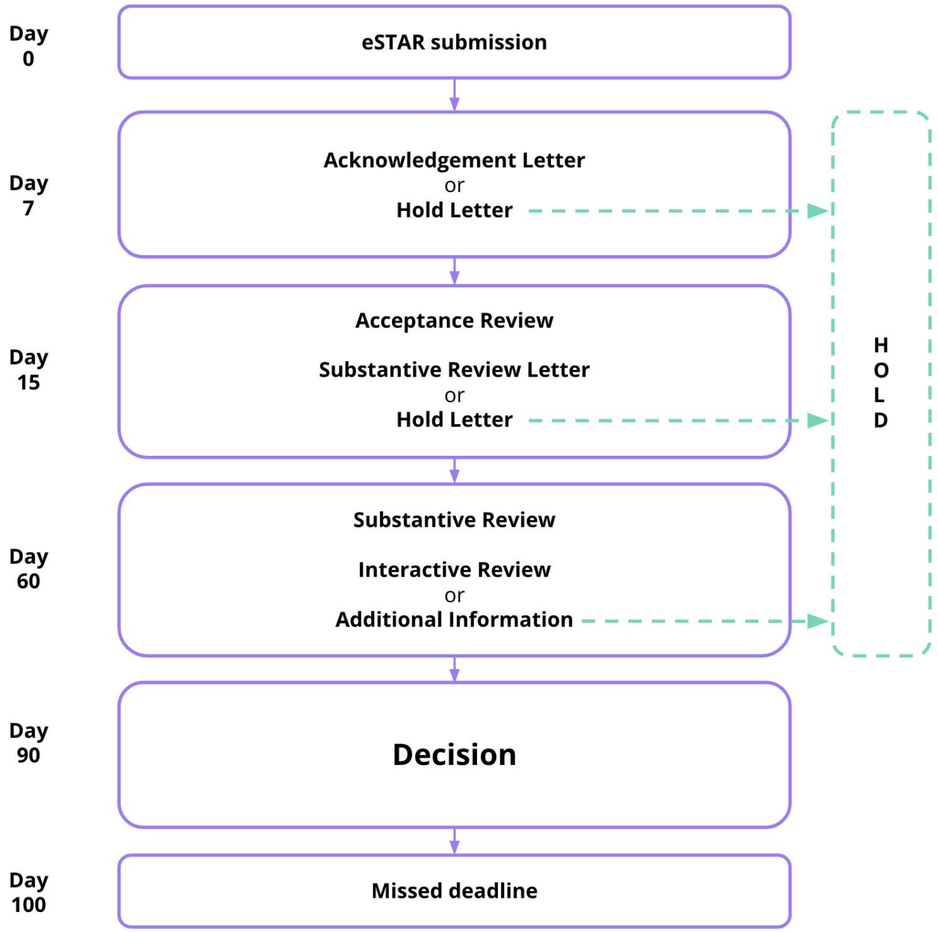
Based on a predicate device already cleared through de novo or PMA.

This is a short 90 day* application that details your device's performance and how it compares to a similar device that is already on the market.

Cost: $22K ($5K for small businesses)

*Timeline: 90 days of FDA work - but usually takes longer

510(k) - timeline



De Novo - no predicate

Low to moderate risk novel devices.

FDA will review De Novo requests for devices that are not within a device type that has been classified under the criteria at section 513(a)(1) of the FD&C Act. This includes devices that do not fall within any existing classification regulation, where the De Novo requester or FDA determines that there is no predicate device.

Upon successful review of a de novo submission, the FDA creates a classification for the device, a regulation if necessary, and identifies any special controls required for future premarket submissions of substantially equivalent devices.

Cost: $145K ($36K for small businesses)
Timeline: 150 days +

PMA - novel high risk

High risk novel devices (Class III)

Process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices, and the most stringent of the device marketing applications.

Costs: $484K ($121K for small businesses)

Timeline: 250 days average

Australia - TGA

Therapeutic Goods Administration acts much like the FDA as a sole regulator.

Regulatory framework very similar to the EU, though with more stringent review and a tendency to up-class devices. TGA does encourage pre-submissions.

Costs: QMS $33K, £45K audit

Timeline: 190 - 225 business days

Canada

Health Canada acts much like the FDA as a sole regulator.

Regulatory framework aligned with the EU, but with the addition of Clinical Decision Support exemptions (as per FDA).

If you sell or import any class of medical devices in Canada, you must apply for and maintain a Medical Device Establishment Licence (MDEL) for your business and a Medical Device Licence (MDL) per device)

Costs: MDEL $5K, MDL Class II licence= $522 Class III licence= $10K (discounts for small businesses)

Timeline: 190 - 225 business days

United Arab Emirates

To access the UAE foreign medical device manufacturers must register both the manufacturing site and the medical device with the **UAE Ministry of Health and Prevention** (MOHAP) via the **Registration and Drug Control Department** (DRCD).

The requirements for UAE device registration broadly follow recognised regulations such as the EU and US FDA.

There is a simplified registration process for devices which have received approval from recognized country including Europe, the US, Australia, Canada, or Japan.

As with most international markets foreign manufacturers must appoint a licensed and authorised representative residing within the UAE to act as their Authorized Representative

South Korea

All companies planning to sell a medical device in South Korea must register their product with the **Ministry of Food and Drug Safety** (MFDS).

There are three market authorization pathways, depending on the device classification.

All devices without a substantially equivalent predicate device in South Korea require clinical data review as part of the registration process.

Must appoint a local South Korea License Holder (KLH) to act as your Authorized Representative

Medical Device Single Audit Program (MDSAP)

- Therapeutic Goods Administration of **Australia**
- **Brazil**’s Agência Nacional de Vigilância Sanitária
- Health **Canada**
- **Japan**’s Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency
- **U.S.** Food and Drug Administration
- Korea, China, UK are members of the working group, but not committed to the programme

Medical Device Single Audit Program (MDSAP)

MDSAP covers your QMS only, and is based on a three-year audit cycle:

Initial Audit - The Initial Certification Audit is a complete audit of a medical device manufacturers Quality Management System (QMS).

Year One - Surveillance Audit

Year Two - Surveillance Audit

Year Three - Re-Certification Audit

Contact:

hugh@hardianhealth.com

Hin.mindset@nhs.net

Hardian Health

Clinical | Digital | Consulting

www.hardianhealth.com

@HardianHealth

UKRI Innovate UK

hin Health Innovation Network South London