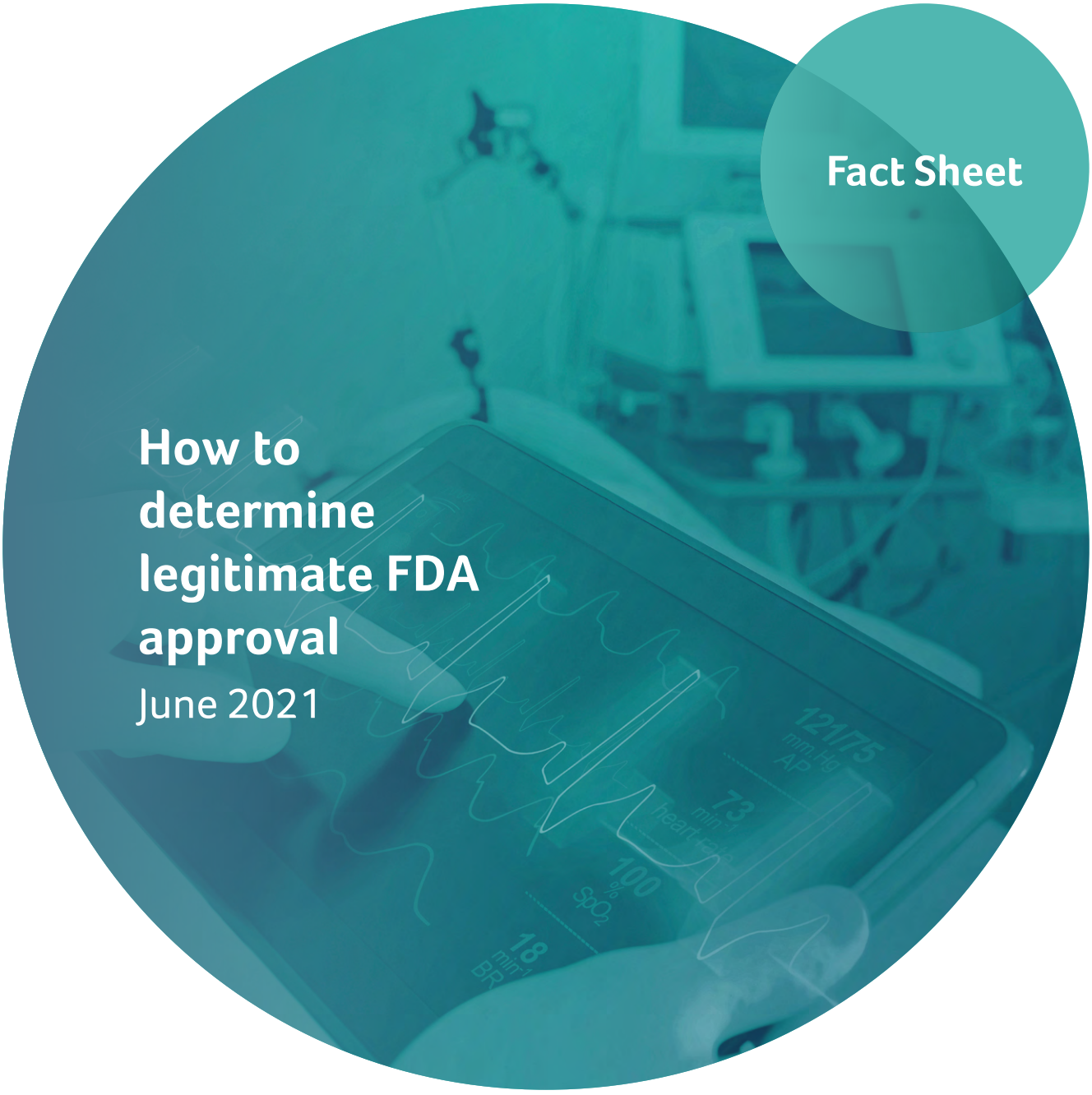
Congenius



Fact Sheet

How to determine legitimate FDA approval

June 2021

Smart consulting,
enhanced medical solutions.

How to determine legitimate FDA approval

The terms **“FDA registered”**, **“FDA certified”** and **“FDA Registration Certificate”** do **NOT** mean the same as **“FDA approved”**, **“FDA cleared”** or **“FDA authorised”**, even if they appear with the FDA logo.

This fact sheet outlines the important differences between this terminology related to medical devices.

“FDA Registered” | What registration with the FDA really means

Generally, if you are an owner or operator of a place of business (also referred to as an establishment or facility), that is involved in the production and distribution of medical devices intended for use in the US, you are required to register annually with the FDA.

When a facility registers its establishment and lists its devices, the resulting entry in the FDA's registration and listing database does NOT denote approval, clearance, or authorisation of that facility or its medical devices.

Click **here** for information on medical device establishment registration.

“FDA Certified” & “FDA Registration Certificate” | Are there FDA certificates?

Some firms that sell medical devices in the US publicise "**FDA registration certificates**". These certificates often have the look of an official government document and may include the FDA logo.

When a business involved in the production and distribution of medical devices intended for use in the US registers with the FDA, they do **NOT** receive a certificate from the FDA.

The FDA does **NOT**:

- **Issue any type of device registration certificates to medical device facilities**
- **"Certify" registration information for businesses that have registered and listed**

Firms that misleadingly display certificates alongside information about medical devices for sale in the US to imply the FDA’s review or approval of the device, misbrand the device in violation of the Federal Food, Drug, and Cosmetic Act.

Furthermore, the **misuse of FDA’s logo** may violate federal law. FDA’s logo is for official government use only and should not be used to misrepresent the agency or to suggest that FDA endorses any private organisation, product, or service.

How do you know if the FDA has approved, cleared, or authorised a medical device?

The FDA provides several ways for you to check whether a medical device is “FDA approved” or “FDA cleared”:

Check for approved and cleared products in the Devices@FDA database

Devices@FDA is a catalogue of approved and cleared medical device information from the FDA. To search for FDA-approved or FDA-cleared products by device name or company name simply follow the steps below:

Go to the **Devices@FDA** Database	Type the device name / category or company name in the **Enter a search term in the space below** field	**Click Search**

Check for products in the De Novo database

The **De Novo** classification process is a regulatory pathway for new types of low-to-moderate-risk devices. Devices reviewed through this pathway may be authorised for marketing in the US. To search for products by device name or company name follow the steps below:

Go to the **Device Classification Under Section 513(f)(2)(De Novo)** database	Type the device name in the **Device Name field** **OR** Type the company name in the **Requester Name field**	**Click Search**

Check for Emergency Use Authorisations

During certain types of public health emergencies such as the COVID-19 pandemic, when the Secretary of Health and Human Services declares that circumstances justifying the authorisation of emergency use of medical devices exist, the FDA may issue an **Emergency Use Authorisation (EUA) to authorise unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain criteria are met.** You can check medical device EUAs **here**.

Should you require assistance with a regulatory challenge, please don’t hesitate to get in touch – we’d be happy to help.

Congenius AG
Riedstrasse 1
CH-8953 Dietikon

congenius.ch