

Private Labeling of Medical Devices in the United States



NICE TO MEET YOU!

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Session Agenda

- Introduction to Private Label Medical Devices
 - Key Definitions
 - Types of Private Label Medical Devices
 - Regulatory Considerations
- Establishment Registration & Device Listing
- Labeling Requirements
 - Unique Device Identification (UDI)
- Relationships and Responsibilities
- Advantages of Using Private Labels
- Best Practices
- Q/A

Introduction to Private Label Medical Devices

What Are Private Label Medical Devices?

A “**private label**” medical device is a medical device that can be identical in all respects to a device manufactured by an **original manufacturer or original equipment manufacturer (OEM)**, except that it is labeled with **the private labelers** name, address, product name, and identifier.

This enables multiple companies to bring similar or identical devices to market under distinct branding, while the OEM maintains control over design and production.

In this arrangement, the company selling the device, referred to as the **private label distributor (PLD)**, is not the actual manufacturer but markets and distributes the device under its own name or trademark.

Key Definitions

Manufacturer

“... Any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.”

- FDA 21 820.3 (o)

- **Original manufacturer** → Has the same meaning as “**manufacturer**” in these regulations.

Private Label Medical Device → Refers to a medical device that can be identical in all respects to a device manufactured by an OEM, except that it is labeled with the private labeler's name, address, product name, and identifier.

- **Private labeler** or **Private Label Distributor** → A company that sells a private label medical device under its own name or trademark.

Types of Private Label Medical Devices

- **White Label:** Private label medical devices are private label medical devices that are manufactured by an OEM for a private labeler that offer **less customizations, usually generic**, which are sold to multiple private labelers
 - These are **typically low risk devices**.
- **Black Label:** Private label medical devices that are manufactured by an OEM **specifically for a single private labeler** and may involve **customizations or modifications** to meet that labeler's unique requirements.
 - These are typically **exclusive-use devices** under a single brand.

Regulatory Considerations

- The process of private labeling a medical device is negotiated directly between the **private labeler** and the **original manufacturer**.
 - A robust **supplier management process**, including clear roles, responsibilities, and quality agreements, between both parties is essential to ensure compliance and product quality.
- It is important to note that the **FDA is not directly involved** in the private labeling process.
 - Private label arrangements must still comply with all applicable FDA regulations, such as device registration, complaint handling, adverse event reporting, recall procedures, labeling and importing.

Regulatory Considerations

The specific regulatory pathway will depend on the **device classification** and **product code**, and may involve a **510(k) premarket notification, De Novo classification, PMA submission**, or other applicable regulatory route.

Accurately identifying the device's classification and product code is essential for determining the appropriate regulatory pathway.

In many cases, a private label distributor is not required to submit a new 510(k) if the original OEM has a cleared 510(k) for the device, and there are no changes to the device's intended use, performance, function, or technological characteristics.

OEM must list the device correctly under its FDA registration, and the private labeler must also be properly registered and listed with the FDA.

Establishment Registration & Device Listing

Responsibilities of a Private Labeler

Even though a Private Labeler doesn't manufacture the device, they must still comply with **FDA regulations around establishment registration and device listing**.

- If a Private Labeler only distributes devices and does not engage in manufacturing, repackaging, relabeling, or act as the initial importer, may not need a separate registration or listing as a distributor or relabeler.
 - However, the manufacturer/specification developer of the device must be registered and listed per 21 CFR 807.
- Additionally, they must **list the device** under their own name in the FDA's system, but they won't achieve a new 510(k); instead, it would be referenced the Original Manufacturer's clearance or exemption.
 - This requires authorization from the Original Manufacturer.

Responsibilities of a Private Labeler

- The FDA doesn't allow the same device to be listed under multiple 510(k)s unless it's been legally re-cleared. So typically, private labelers "**piggyback**" off the Original Manufacturer's submission.

*A **new 510(k)** is only required for re-clearance such as the private label device contains significant changes or which impact the device performance, function, and intended use.*

Establishment Registration & Device Listing

Domestic Original Manufacturer

U.S. Based

- Responsible for listing in FDA's United Registration and Listing System (FURLS)
 - Add private label brand name to device listing
 - Identify private labeler as **distributor**, not manufacturer

Establishment Registration & Device Listing

Foreign Original Manufacturer Outside of U.S.

- Must register as a foreign establishment
- Must designate a U.S. Agent
- Private labeler/distributor must:
 - *Be listed as "Importer" in FURLS*
 - *Ensure import compliance and labeling accuracy*

Labeling Requirements

21 CFR Part 801 Requirements

801.1 (a)

- *"The Label of a device in package form shall specify conspicuously the name and place of business of the manufacturer, packager, or **distributor**"*

801.1 (c)

- *"Where a device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such device; such as, "**Manufactured for ___**", "**Distributed by _____**", or any other wording that expresses the facts." (e.g., "Manufactured for XYZ Corp.", "Distributed by XYZ Corp.")*

Device may be misbranded if:

- Label misrepresents the true manufacturer, packager, or distributor
- Private labeler hasn't listed the device or registered
- Claims exceed the cleared 510(k)

Unique Device Identification (UDI)

UDI is required on the Device Label and Packaging.

Per FDA 21 CFR Part 830 & 801.20

- Must include UDI in both **human-readable** and **machine-readable** (AIDC) format.
- Applies to all finished labeled devices, including private label devices.



Labeler Responsibilities for UDI

The Labeler is Responsible For:

- **UDI compliance** (typically the private labeler if their name appears on the label)
- Ensuring the UDI is properly assigned and issued by an FDA-accredited issuing agency
- Submitting UDI to the **Global Unique Device Identification Database (GUDID)**

Labeler Responsibilities for UDI

White Labels

OEM may handle UDI, especially if multiple brand variants share the same DI.

Black Labels

UDI is **specific to the private labeler's branded version**, so a new Device Identifier (DI) is often required.

Regardless of which party is identified as the responsible labeler, they would also be responsible for UDI.

Scenario	Labeler (Owns Label)	UDI/GUDID Responsibility	Label Control (QMS)	GTIN / DI Issuance
<i>OEM manufactures and distributes under own brand</i>	OEM	OEM creates UDI-DI, submits to GUDID	OEM controls label design/approval under its QMS	OEM issues GTIN/DI for distinct model/version
<i>OEM manufactures private-label version; OEM prints label, but private brand appears</i>	Private labeler (brand on label)	Private labeler must create UDI-DI and submit GUDID	OEM controls printing under supervision; private labeler approves final label	Private labeler issues separate GTIN/DI, even for identical device
<i>Private labeler repackages, relabels, or reprocesses</i>	Private labeler	Private labeler must issue new UDI and file GUDID	Private labeler manages labeling under its QMS	New GTIN/DI required for relabeled version
<i>OEM identified as manufacturer; private labeler only specifies branding, but OEM is still on the label</i>	OEM remains labeler (private brand is secondary)	OEM retains UDI/GUDID submission responsibility	OEM QMS fully controls labeling	No new GTIN/DI (brand remains OEM's identifier)
<i>OEM sells identical product under multiple private brands for different labelers</i>	Each private labeler is a distinct labeler for their brand	Each private labeler must create and register their own UDI/DI (GUDID entries)	OEM prints per brand; labeler approves and controls their labels	Each brand requires distinct GTIN/DI, regardless of identical product
<i>Private labeler markets under their brand but doesn't control packaging or labeling processes</i>	Private labeler still the labeler if brand appears, regardless of control over printing	Labeler (private company) is responsible for UDI/DI, can delegate submission to OEM or 3rd party	OEM handles physical printing; private labeler retains approval authority	Private labeler issues their own GTIN/DI; distinguishes supply chain and recalls
<i>OEM supplies device for multiple private labels under same device version</i>	Private label distribution: each private labeler named on product label is considered labeler	Each private labeler must list and register independently, even if OEM manufactures identically	OEM prints and packages per brand, but labeler must review/approve	Separate GTIN/DI per private label brand and supply channel

Key Relationships & Responsibilities in Medical Device Private Labeling

Key Relationships & Responsibilities

- There is **no one-size-fits-all approach to defining responsibilities in private label medical device relationships.**
- Each partnership between a Private Labeler and OEM is **unique** and must be tailored based on:
 - Nature of the device
 - Regulatory responsibilities
 - Commercial arrangements.
- The key is to establish a robust **Supplier Quality Agreement (SQA)** → Most critical tool for clearly outlining regulatory and operational responsibilities early in the relationship, helping to prevent:
 - Compliance gaps,
 - Misunderstandings
 - Operational conflicts

Supplier Quality Agreement (SQA)

A robust **Supplier Quality Agreement (SQA)** is essential for private label arrangements, serving as the foundation for assigning and documenting quality and regulatory responsibilities between the Original Manufacturer and private labeler.

An Effective SQA should include:

- Detailed scope of the relationship and regulatory context
- Roles and responsibilities for design, production, labeling, and post market activities
- Quality system requirements (e.g., document control, CAPA, internal audits)
- Complaint handling and MDR responsibilities
- Procedures for change control, including required notifications
- Expectations for audits, record retention, and regulatory inspections
- Clear processes for recall coordination and field actions

The SQA should be reviewed periodically, especially in response to changes in regulations (e.g., FDA's transition to QMSR), product scope, or supplier performance. A well-maintained SQA protects both parties and is often scrutinized during FDA inspections.

Example SQA Inclusion

Section X: Private Labeling Responsibilities

Section X.1. Regulatory Authority

The "Manufacturer" (ORIGINAL MANUFACTURER) shall maintain legal ownership and control of all applicable FDA regulatory submissions, including but not limited to 510(k) premarket notifications and technical documentation for the device(s) covered by this agreement.

Section X. 2. Labeling and Branding

- a) The Private Labeler (COMPANY) shall provide final label artwork, including name, address, product name, and branding elements, for ORIGINAL MANUFACTURER approval prior to initial commercial distribution.*
- b) The label must include the phrase "Manufactured for" or "Distributed by" as required under 21 CFR 801.1(c).*
- c) The COMPANY agrees not to label the device with the ORIGINAL MANUFACTURER's information without prior written approval.*

Example SQA Inclusion

Section X.3. Establishment Registration & Device Listing

- a) *The Private Labeler is responsible for registering their establishment with the FDA and ensuring the device is appropriately listed under their name via cross-reference to the ORIGINAL MANUFACTURER's product code and 510(k) number.*
- b) *The ORIGINAL MANUFACTURER shall grant authorization via FURLS or written letter to allow listing by the Private Labeler.*

Section X.4. Unique Device Identification (UDI)

The Private Labeler is responsible for submitting UDI records to the FDA's GUDID under their labeler account and ensuring alignment with the device listing.

Section X. 5. Complaints, Adverse Events & Recalls

The ORIGINAL MANUFACTURER retains responsibility for complaint handling, MDR reporting, and recalls, unless otherwise stated. The Private Labeler agrees to forward all customer complaints or adverse event reports within [X] business days to the ORIGINAL MANUFACTURER.

Advantages of Using Private Labels

Private labeling offers several strategic advantages for companies entering or expanding within the medical device market.

- **Brand Market Ownership**

- Private labelers can offer FDA-cleared devices under their branding without the need to invest in product development or manufacturing infrastructure.
- Allows companies to quickly establish or expand their product portfolio and strengthen brand recognition in their target market.

- **Enables Prioritized Market Access**

- Reduces time-to-market and allows companies to focus on core competencies such as marketing, sales, and customer service while relying on experienced manufacturing for production and regulatory compliance.

- **Provides flexibility in supplier selection and diversification**

- Businesses can concentrate on marketing, sales, and customer support, while relying on experienced manufacturers for production and regulatory compliance.

Overall, private labeling serves as a **cost-effective, scalable, and lower-risk strategy** for commercial growth in the medical device sector.

Best Practices

1. Establish a Robust Supplier Quality Agreement (SQA)
2. Ensure Proper FDA Registration & Device Listing
3. Comply with Labeling and UDI Requirements
4. Define Complaint Handling and MDR Reporting Processes
5. Implement Change Control and Communication Protocols
6. Address Import and Customs Compliance (if applicable)
7. Monitor Regulatory Updates and Adapt Agreements
8. Prepare for Relationship Transitions or Terminations

Do You Have Any Questions?



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