



**LEARNING UDI
COMMUNITY**



AHRMM

Association for Healthcare
Resource & Materials Management

Advancing the Healthcare Supply Chain

A professional membership group of the
American Hospital Association

Low Unit of Measure (LUM) UDI Single Device Work Group Report Supply Chain Best Practices: LUM and UDI Implementation



LEARNING UDI
COMMUNITY

WWW.AHRMM.ORG / LUC

LUM UDI WORK GROUP REPORT

PURPOSE:

The goal of this document is to provide a guide for supply chain partners to begin a dialogue to ensure that medical devices comply with FDA's Unique Device Identification (UDI) requirements as well as meet the FDA's goal of enhancing patient safety. Low Unit of Measure (LUM) programs are complex and the steps outlined in this best practices document are a critical first step. We expect this to be an ongoing process as additional opportunities for stakeholder collaboration continue to arise.

On September 24, 2013, the FDA issued the final Unique Device Identifier (UDI) rule intended to adequately identify medical devices through their distribution and use. UDI includes a series of numeric or alphanumeric characters that have been assigned to a product as a Device Identifier (DI). UDI also may include one or more Production Identifier(s) (PI) (lot, expiry, etc.) along with the DI on the medical device packaging label and on the device itself in both a machine readable and human readable format. There are also requirements on submitting essential product data into the Global Unique Device Identification Database (GUDID) database and to use UDI across the device lifecycle. (Please refer to the FDA UDI regulation for complete details.)

The UDI Rule applies broadly to all medical devices. However, because of the diversity and complexity of medical devices, FDA has offered limited alternatives, extensions, and exceptions to the UDI regulatory requirements. The FDA Single-Use Device Exception¹ coupled with an evolving Low Unit of Measure (LUM) market created the need for further examination of UDI practices in the healthcare supply chain around this device distribution model. At the request of HIDA and several distributors, FDA granted a two-year extension for medical device distributors and manufacturers to revisit their respective UDI implementation efforts and to further collaborate to ensure that the UDI requirements are still being met after products have been removed from the device package that contains multiple devices of the same model/version by the distributor for LUM distribution.

BACKGROUND:

Low Unit of Measure/Just in Time Programs (LUM/JIT):

LUM and JIT programs are used by medical device distributors to better support healthcare provider needs for improved efficiencies and better patient care by:

- Allowing products to go directly to patient care areas
- Optimizing provider inventory levels to improve cash flow
- Maximizing provider focus on the delivery of care
- Reducing total costs of doing business as well as see a reduction of material and waste



¹ Single-Use Device General Exception § 801.30 (a)(3)

Individual single-use devices, all of a single version or model, that are distributed together in a single device package, intended to be stored in that device package until removed for use, and which are not intended for individual commercial distribution. This exception is not available for any implantable device. The device package containing these individual devices is not excepted from the requirement of § 801.20, and must bear a UDI.

LUM UDI WORK GROUP REPORT

LUM Challenge Related to UDI: The FDA UDI regulation requires that devices be adequately identified through distribution and use. LUM programs may result in the device being removed from the UDI compliant packaging by the distributor in order to provide individual products to healthcare providers to enhance patient care. Once the device is removed from the package, it may no longer meet UDI compliant packaging standards if the device is not originally labeled at the “each” level. Manufacturers and distributors need to collaborate to ensure that FDA’s UDI requirements are being met for the products that are distributed via LUM programs.

RECOMMENDED LUM/SINGLE-USE DEVICE UDI ASSURANCE PROCESS:

Communication is essential for distributors and manufacturers to develop meaningful plans to comply with UDI regulations. Accurate data and a clear understanding of distributor LUM programs are essential inputs for a successful UDI implementation. Device manufacturers need an understanding of distributor programs and needs in order to further implement UDI in a way that safely supports LUM programs. The process below can assist in creating a clear mutual understanding to ensure UDI compliance in the healthcare supply chain.

STEP #1: Initiate Trading Partner Discussion

The distributor and manufacturer need to mutually understand the distributor’s LUM programs and develop a plan to comply with UDI. Anti-trust considerations necessitate that these conversations be conducted one-on-one between individual trading partners.

STEP #2: Share Key Data

Distributor to share a list of products distributed in LUM/JIT programs. Data needs may vary by trading partner relationship.

STEP #3: Analysis

Manufacturer to review distributor data. Manufacturer to gather up-to-date UDI implementation plans from their product teams based on the distributor’s data. The device manufacturer to determine if/when gaps exist as a result of LUM distribution. The device manufacturer should also assess the suitability of products in a LUM program.

STEP #4: Dialogue

Manufacturer to provide distributor with a response of how they are preparing for UDI for products sold via LUM programs. The device manufacturer should provide a summary of the status of the product line in advance of the applicable FDA UDI product compliance date. Discussions may necessitate:

- **Deeper data dive:** Initial discussion may highlight the need for additional information to determine the best UDI solution.
- **Provider input:** Frequency of their usage in LUM programs and may trigger the need for discussions with healthcare providers to understand more about the impact on patient care. Additionally, healthcare provider input and reimbursement requirements may indicate why products are being distributed via LUM programs.

STEP #5: Develop a Plan

Manufacturer and distributor to decide on how to proceed with UDI implementation and determine how to communicate to their provider customers.

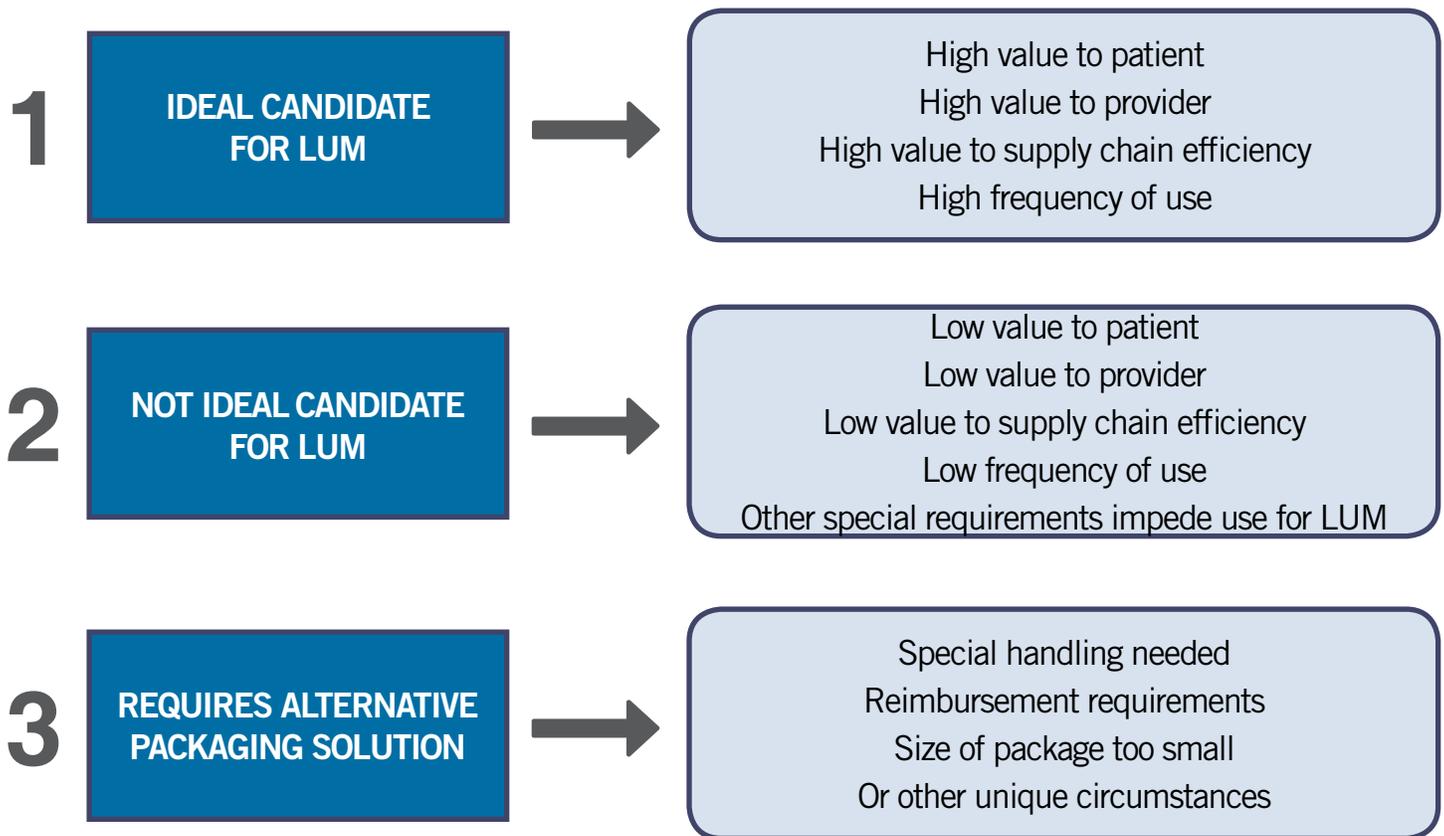
LUM UDI WORK GROUP REPORT

STEP #6: Continued Dialogue

Plans change. Markets evolve. Distributors and manufacturers should maintain continued dialogue and ensure that the FDA UDI requirements are being met and that all applicable label regulations are being maintained.

POSSIBLE SOLUTIONS TO ENSURE UDI COMPLIANCE:

The AHRMM LUC UDI Work Group identified three possible scenarios for managing products that have been removed from their UDI compliant packaging by a distributor for a LUM program. The three scenarios are:



SUMMARY:

LUM is a growing market trend that healthcare providers value. The FDA UDI regulation is here to stay and device manufacturers and distributors must ensure that all applicable regulations are being adhered to. Communication and the sharing of information between trading partners are essential. At the end of these discussions, distributor, and device manufacturers should develop a plan that specifies what each organization is responsible for. Medical device distributors and manufacturers have traditionally collaborated to meet market needs and we expect that the same spirit will carry over into the LUM challenge that we are currently facing.

Legal Disclaimer: The contents of this best practices document are not intended as legal advice nor as legally binding, and should not be construed or acted upon as such.

LUM UDI WORK GROUP REPORT

APPENDIX

Type of Device	Label (21 CFR 801.20), GUDID Submission (21 CFR Part 830, subpart E), and Standard Date Format (21 CFR 801.18) Requirements	Direct Mark (21 CFR 801.45) Requirements
Class I devices***	September 24, 2018	September 24, 2022
Certain class II devices**	September 24, 2018	
Unclassified devices	September 24, 2020	September 24, 2022

For implantable, life-supporting or life-sustaining devices of all classes, the compliance date for all UDI requirements and the standard date format requirement (21 CFR 801.18) was September 24, 2015.

**The FDA extended this deadline from September 24, 2016 to September 24, 2018. This is not a blanket extension for all class II devices. Instead, it refers to device constituent parts of certain combination products, repackaged class II single-use devices that are not individually labeled with a UDI (i.e. single-use devices broken down to the each for low unit of measure), and collections of two or more different class II, or class II and class I, devices packaged together in which the devices in the package are not individually labeled with a UDI.

*** <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM592340.pdf>

GENERAL EXCEPTIONS:

Under § 801.30, the UDI rule provides general exceptions from UDI labeling requirements to certain categories of devices. A device within one or more of these exceptions is not required to bear a UDI. A labeler of a device identified in § 801.30 is not required to request an exception from FDA. The final rule:

§801.30(a)(1)	Provides an exception for a finished device that is manufactured and labeled prior to the compliance date that applies to that device (exception expires 3 years after the compliance date)
§801.30(a)(2) <i>*see table on page 6</i>	Provides an exception for a class I device that FDA has by regulation been exempted from the good manufacturing practice (GMP) requirements*
801.30(a)(3)	Provides an exception for certain individual single-use devices (SUDs), regardless of class, except that this exception is not available for any implantable device - the device package containing these individual devices must bear a UDI
§801.30(a)(11)	Excepts the device constituent part packaged within a combination product from the requirement that its label bear a UDI, if the combination product bears a UDI
§801.30(a)(11)	Does not require devices contained within a convenience kit to bear a UDI but does require the label and each device package of every convenience kit to bear a UDI
§801.40(d)	Provides that a class I device labeled with a Universal Product Code (UPC) may use the UPC as its UDI

LUM UDI WORK GROUP REPORT

Product Code	Examples of Class I Devices Exempted from GMP Requirements Product Preferred Name
FOB	Bedpan
ILI	Arm Sling
IPR	Crutch
ITJ	Mechanical Walker
KIZ	Tissue Culture Dish

*For full list visit:

<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UCM382498.pdf>

USEFUL LINKS:

Product Classification Database:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>

FDA UDI Rule:

<https://www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23059.pdf>

FDA Letter to Device Labelers (September 6, 2016):

<https://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM519346.pdf>

FDA UDI Help Desk:

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm>

Compliance Dates for UDI Requirements:

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/CompliancedatesforUDIRequirements/default.htm>

THANK YOU TO THE FOLLOWING WORK GROUP MEMBERS:

Alex Caldwell, Claflin

Jodi King, Philips

Bill Crates, Cardinal Health

Kathleen Devaney, Henry Schein

Billy Almon, Claflin

Kevin Neuman, Innovative Healthcare Corporation

Bryan Fagnani, Lynn Medical

Kyle Gurney, VCU Health

Carl Kennedy, ThermoFisher

Lena Cordie, Qualitas Professional Services, LLC.

Carlos Chaparro, Bowie

Linda Rouse O'Neill, HIDA

LUM UDI WORK GROUP REPORT

Carol Baum, Medline

Claire Mansbach, HIDA

Curt Wilens, Cardinal Health

Dennis Black, BD

Doug Caro, McKesson

Elizabeth Valentine, Owens & Minor

Ellenmary Martin, Dukal

Erin Salbilla, Vyair

Frank Pokrop, CareFusion

Gary Tiamsic, Henry Schein

Greg Laird, NDC

Indira Konduri, FDA

Jay Crowley, USDM Life Sciences

Jeff Peacock, Henry Schein

Jim Booker, Stanford Health Care

Loretta Chi, FDA/CDRH/OSB/Informatics

Mary Gray, Johnson & Johnson

Matt Shiraki, McKesson

Michael Oliver, Clafin

Mike Marchlik, Owens & Minor

Mike Nolan, AIS

Peter Sadler, Henry Schein

Rich Paul, Henry Schein

Ryan McBee, DeRoyal

Sergio Tejeda, Henry Schein

Shari Bouche, Cardinal Health

Tim Fenton, ThermoFisher

Tim Sleddens, Cerner Corporation

Zita Yurkom, Philips

Blair Korman, Johnson & Johnson