UDI Exceptions and Alternatives

The UDI rule provides a method for labelers to request exceptions and alternatives to UDI requirements.

On this page:

Exceptions and Alternatives Granted by FDA

Under to 21 CFR 801.55(c), any labeler may make use of an exception or alternative granted under § 801.55 (https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system#p-501), provided that such use satisfies all safeguards or conditions that are part of the FDA exception or alternative decision.

Labelers should refer to the information in the table below, especially in the "FDA Decision" column, to determine if an exception or alternative listed may apply to their situation. Labelers may document the applicability and use of an exception/alternative in the device master record (DMR) (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=820.181) as part of the labeling specifications required under 21 CFR 820.181(d) for each respective device, along with a copy of the applicable exception or alternative decision.

FDA UDI Exception or Alternative Number	Summary	FDA Decision	Expiration Date of Exception or Alternative	Date of Posting
UDI-A160001	UPC - multiple product codes	Decision (/medical-devices/unique-device-identification-system-udi-system/fda-udi-alternative-udi-a160001)	2023-09-24	2021-07-29
UDI-A160002	UPC - contact lens care	Decision (/medical-devices/unique-device-identification-system-udi-system/fda-udi-alternative-udi-a160002)	2023-09-24	2021-07-29
UDI-A170001	Sterile inventory; 3-year exception; 21 CFR 801.30(a)(1)	Decision (/medical-devices/udi-exceptions-alternatives-and-time-extensions-section/fda-udi-alternative-udi-a170001)	2024-09-24: Class III; 2025-09-24: I/LS/LS; 2026-09-24: Class II	2019-04-29
UDI-E140001	Soft (hydrophilic) contact lenses	Decision (/media/104454/download)	One year after FDA: 1) develops and fully integrates the Technical Solution into the GUDID production system, 2) provides any necessary updated technical specifications to affected labelers, and 3) notifies industry that the extension will expire, through emails to industry, communication via trade associations, and via the UDI website.	2017-03-30

FDA Product Codes for UDI Alternative UDI-A160001

Version 1.8: June 22, 2022

FDA Product Code	FDA Product Code Name	Regulation (21 CFR)
EBO	Over the Counter Denture Repair Kit	872.3570
EBP	Reliner, Denture, Over the Counter	872.3560
EMA	Cement, Dental	872.3275
FLK	Thermometer, Clinical Mercury	880.2920
FLL	Thermometer, Electronic, Clinical	880.2910
FMF	Syringe, Piston	880.5860
FMI	Needle, Hypodermic, Single Lumen	880.5570
FRO	Dressing, Wound, Drug	N/A
GZJ	Stimulator, Nerve, Transcutaneous, for Pain Relief	882.5890
HEB	Tampon, Menstrual, Unscented	884.5470
HHE	Cup, Menstrual	884.5400
HHW	Pessary, Vaginal	884.3575
HIL	Tampon, Menstrual, Scented, Deodorized	884.5460
HIS	Condom	884.5300
ILY	Lamp, Infrared, Therapeutic Heating	890.5500
KKO	Ring, Teething, Fluid-Filled	872.5550
LBH	Varnish, Cavity	872.3260
LCX	Kit, Test, Pregnancy, hCG, Over the Counter	862.1155
LDJ	Enzyme Immunoassay, Cannabinoids	862.3870
LFD	Saliva, Artificial	N/A
LKY	Device, External Penile Rigidity	876.5020
LPN	Accessories, Soft Lens Products	886.5928
LRR	First Aid Kit with Drug	N/A
LRX	Case, Contact Lens	886.5928
LTZ	Condom with Nonoxynol-9	884.5310
LYL	Accessories, Solution, Ultrasonic Cleansers for Lenses	886.5928
MNW	Analyzer, Body Composition	870.2770
MSC Added 06/23/2022	Barrier, STD, Oral Sex	884.5300
MOL	Condom, Synthetic	884.5300
MRC	Products, Contact Lens Care, Rigid Gas Permeable	886.5918
NUC	Lubricant, Personal	884.5300
NUH	Simulator, Nerve, Transcutaneous, Over-the-Counter	882.5890
OBR	Mouthguard, Over-the-Counter	N/A
OHT	Light Based Over-the-Counter Hair Removal	878.4810
PEB	Lubricant, Personal, Gamete, Fertilization, and Embryo Compatible	884.5300
POV	Semen Analysis Device	864.5220
QRZ Added 06/22/2022	External Condom for Anal Intercourse or Vaginal Intercourse	884.5305

FDA Product Codes for UDI Alternative UDI-A160001 - Document History

Version	Date	Change
1.0	August 19, 2016	Original

1.1	September 6, 2016	Added the following FDA Product Codes: FLK, FLL, LPN, LRX, LYL, and MRC
1.2	October 5, 2016	Added the following FDA Product Code: MNW
1.3	November 30, 2016	Added the following FDA Product Code: ILY
1.4	January 11, 2017	Added the following FDA Product Code: POV
1.5	January 4, 2018	Added the following FDA Product Code: LFD
1.6	June 28, 2018	Added the following FDA Product Code: HHE
1.7	November 5, 2021	Added the following FDA Product Codes: GZJ and OBR
1.8	June 22, 2022	Added the following FDA Product Codes: MSC and QRZ

FDA Product Codes for UDI Alternative UDI-A160002

Version 1.0: October 5, 2016

FDA Product Code	FDA Product Code Name	Regulation (21 CFR)
LPN	Accessories, Soft Lens Products	886.5928
MRC	Products, Contact Lens Care, Rigid Gas Permeable	886.5918

FDA Product Codes for UDI Alternative UDI-A160002 - Document History

Version	Date	Change
1.0	October 5, 2016	Original

FDA Product Codes for UDI Alternative UDI-E140001

FDA Product Code	FDA Product Code Name	Regulation (21 CFR)
LPM	Soft (hydrophilic) Contact Lens (extended wear) - Class III Device	886.5925(b)(2)
NCZ	Soft (hydrophilic) Contact Lens (for color vision deficiency) - Class II Device	886.5925(b)(1)
NIC	Soft (hydrophilic) Contact Lens (for reading discomfort) - Class II Device	886.5925(b)(1)
LPL	Soft (hydrophilic) Contact Lens (daily wear) - Class II Device	886.5925(b)(1)
MVN	Soft (hydrophilic) Contact Lens (disposable) - Class II Device	886.5925(b)(1)

Exceptions and Alternatives - General Information and How to Request

General exceptions from the requirement for the label of a device to bear a unique device identifier (UDI) (§ 801.30)

21 CFR 801.30 (https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system#sec-801-30) 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 (https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system#sec-801-30) is not required to request an exception from the FDA.

Request for an exception from or alternative to a UDI requirement (§ 801.55)

A labeler may submit a request for an exception from or alternative to the requirement for the label of a device to bear a unique device identifier (§ 801.20 (https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system#sec-801-20)) or other UDI requirement under 21 CFR 801 Subpart B (Labeling Requirements for Unique Device Identification) (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=801&showFR=1&subpartNode=21:8.0.1.1.2.2) for a specified device or a specified type of device.

In response to labeler requests or on our own initiative, the FDA may grant an exception or alternative if an exception is appropriate because the requirements of 21 CFR 801 Subpart B are not technologically feasible, or that an alternative would provide for more accurate, precise, or rapid device identification than the requirements of 21 CFR 801 Subpart B or would better ensure the safety or effectiveness of the device that would be subject to the alternative. If the FDA grants an exception or alternative, we may include safeguards or conditions deemed appropriate to ensure the adequate identification of the device through its distribution and use. The FDA is making its decisions on labeler requests for exceptions and alternatives available at "FDA Decisions (/medical-devices/unique-device-identification-system-udi-system/udi-exceptions-and-alternatives#decisions)."

Considerations for Labelers

In order to establish a system to adequately identify medical devices through distribution and use, the FDA expects that the labels of almost all devices are capable of bearing and should in fact bear a UDI on the label, unless excepted under 21 CFR 801.30.

Under 21 CFR 801.55(c), the FDA will consider granting requests for an exception from a UDI requirement if the requirement is not technologically feasible. We expect that such situations will be rare. The FDA does not consider exception requests that are based on reasons other than technological infeasibility (including, but not limited to, financial burden or claims of few or no adverse events).

Labelers may consider the following to address issues of inadequate label space, or unique packaging that may create challenges to having the device label bear its UDI in both easily readable plain-text and AIDC forms:

1. Remove or minimize information on the label that is not required under 21 CFR Part 801 (or 21 CFR 809.10, if your device is an in vitro diagnostic product), or otherwise required by regulation or order. See 21 CFR 801.15 for more information on prominence of required label statements.
2. Increase the size of the label or modify the label e.g., move label to a flatter location on the immediate container) to accommodate the UDI.
3. Use a smaller form of AIDC technology or split the AIDC form into multiple segments. The easily readable plain-text UDI may also be split into multiple segments.

If the approaches described above cannot be used to address a labeler's concerns, the labeler may consider submitting a request for an alternative under 21 CFR 801.55 to add an overwrap that would bear the UDI or place another label bearing the UDI elsewhere on the packaging.

To request an exception from or alternative to the requirements of 21 CFR 801 Subpart B:

- Submit a UDI exception/alternative inquiry using the link below. In response, the FDA UDI Help Desk will email instructions for requesting an exception from or alternative to a UDI requirement. If you do not receive an immediate reply in your inbox, please check the spam/junk folder. If the email was diverted to your spam/junk folder, please adjust your filter to recognize the UDI Help Desk as a contact.
- Review the instructions and include the necessary information in your request.
- Submit the request as indicated in the instructions. An FDA UDI Help Desk Analyst will respond to your request.

Submitting Exceptions or Alternatives Requests

Submit New Exception or Alternative Request (https://fdaprod.secure.force.com/exceptionswebform/?subject=New%20Exception%20or%20Alternative%2

(http://www.fda.gov/about-fda/website-policies/website-disclaimer)

According to 21 CFR 801.55(a), when submitting your request for an exception or alternative you must:

- Identify the device or devices that would be subject to the exception or alternative;
- Identify the provisions of 21 CFR 801 Subpart B that are the subject of the request for an exception or alternative;
- If requesting an exception, explain why the requirements of 21 CFR 801 Subpart B are not technologically feasible;
- If requesting an alternative, describe the alternative and explain why it would provide for more accurate, precise, or rapid device identification than the requirements of 21 CFR 801 Subpart B or how the alternative would better ensure the safety or effectiveness of the device that would be subject to the alternative;
- If known, provide the number of labelers and the number of devices that would be affected if the requested exception or alternative were granted; and
- Provide other requested information needed to clarify the scope and effects of the requested exception or alternative.