

serial number, a manufacturing date, an expiration date, or for a human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device, a distinct identification code as required by §1271.290(c) of this chapter, the UDI must include a production identifier segment that conveys such information.

(c) If the AIDC technology is not evident upon visual examination of the label or device package, the label or device package must disclose the presence of AIDC technology.

(d) A class I device that bears a Universal Product Code (UPC) on its label and device packages is deemed to meet all requirements of subpart B of this part. The UPC will serve as the unique device identifier required by §801.20.

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§ 801.45 Devices that must be directly marked with a unique device identifier.

(a) *In general.* A device that must bear a unique device identifier (UDI) on its label must also bear a permanent marking providing the UDI on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use.

(b) *UDI for direct marking.* The UDI provided through a direct marking on a device may be:

(1) Identical to the UDI that appears on the label of the device, or

(2) A different UDI used to distinguish the unpackaged device from any device package containing the device.

(c) *Form of a UDI when provided as a direct marking.* When a device must bear a UDI as a direct marking, the UDI may be provided through either or both of the following:

(1) Easily readable plain-text;

(2) Automatic identification and data capture (AIDC) technology, or any alternative technology, that will provide the UDI of the device on demand.

(d) *Exceptions.* The requirement of paragraph (a) of this section shall not apply to any device that meets any of the following criteria:

(1) Any type of direct marking would interfere with the safety or effectiveness of the device;

(2) The device cannot be directly marked because it is not technologically feasible;

(3) The device is a single-use device and is subjected to additional processing and manufacturing for the purpose of an additional single use.

(4) The device has been previously marked under paragraph (a) of this section.

(e) *Exception to be noted in design history file.* A labeler that decides to make use of an exception under paragraph (d) of this section) must document the basis of that decision in the design history file required by §820.30(j) of this chapter.

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§ 801.50 Labeling requirements for stand-alone software.

(a) Stand-alone software that is not distributed in packaged form (e.g., when downloaded from a Web site) is deemed to meet the UDI labeling requirements of this subpart if it complies with the requirements of paragraph (b) of this section and conveys the version number in its production identifier.

(b) Regardless of whether it is or is not distributed in packaged form, stand-alone software regulated as a medical device must provide its unique device identifier through either or both of the following:

(1) An easily readable plain-text statement displayed whenever the software is started;

(2) An easily readable plain-text statement displayed through a menu command (e.g., an “About * * *” command).

(c) Stand-alone software that is distributed in both packaged form and in a form that is not packaged (e.g., when downloaded from a Web site) may be identified with the same device identifier.

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§ 801.55 Request for an exception from or alternative to a unique device identifier requirement.

(a) A labeler may submit a request for an exception from or alternative to the requirement of §801.20 or any other