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GS1 HUG™ UDI Recommendations

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GS1 HUG™ UDI Recommendations

Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Postmarket Safety Program – Synopsis and Recommendations

2. Develop World Class Data Sources and Systems

We must assess the ability of our current structure to identify postmarket medical device problems and explore new ways to gain access to richer health care data.

As part of this effort, we will champion the development of a system to provide unique device identification, a standardized and globally accepted nomenclature for devices, and mechanisms and incentives for device users to include this information in healthcare records.

C·D·R·H Center for Devices and Radiological Health

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- A globally accepted system
  - GS1 system is globally accepted
  - FDA should contribute to harmonizing medical device identification systems around the world

"Country-specific requirements for labelling text, content, or the format of labels or labelling should be kept to the minimum and, where they currently exist, eliminated as the opportunity arises." (1)

GHTF

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- FDA proposed UDI data elements to include:
  - [1] Manufacturer
  - [2] Make and Model
  - [3] Unique attributes, e.g. size
  - [4] How packaged / supplied
  - [5] SN, LOT, Expiry date, and / or Mfg date

- GS1 Standards include:
  - (01) GTIN contains [1], [2], and [4]
  - (21) contains SN, (10) Lot, (11) Mfg Date, (17) Expiry Date

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- Product (Size) Attributes [3]
  - Medical devices are measured using numerous number systems: English, Metric, French, Gauge, Suture 0-0 USP
  - Many devices have more than one critical dimension
  - Software versions subject to backward-compatible scenarios and should be linked to SN
- Product attributes should be described in database / internet site with UDI/ GTIN pointing to data
- Usage governed by GTIN Allocation rules, e.g. form, fit, and function

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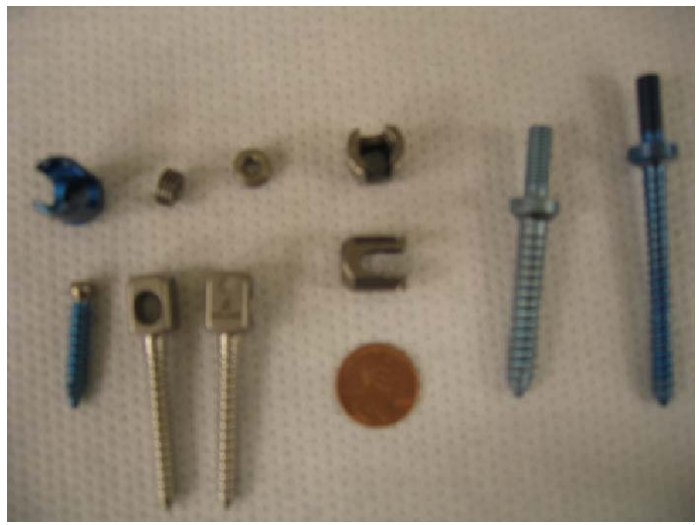
- Data carriers should not be specified by FDA.
  - Bar code symbologies, size, and placement
  - RFID tag size, frequency, and protocol
  - Any carrier approved through the GS1 GSMP / EPCglobal system should be acceptable.



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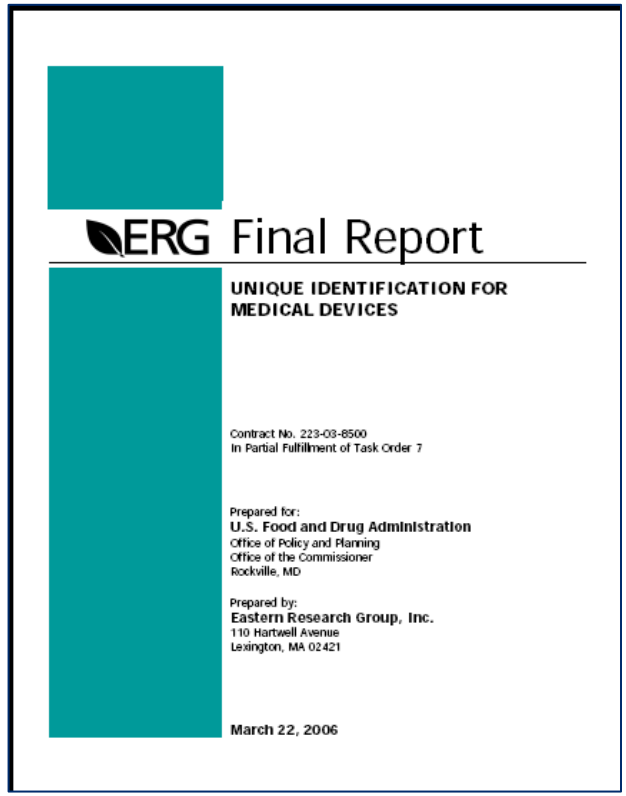
- ERG proposes a mandatory UDI based on both patient safety and supply chain efficiency.
- GS1 HUG™ suggests that commercial and safety attributes may differ.
- GDD and GDSN meet the commercial needs.


ERG Final Report

UNIQUE IDENTIFICATION FOR MEDICAL DEVICES

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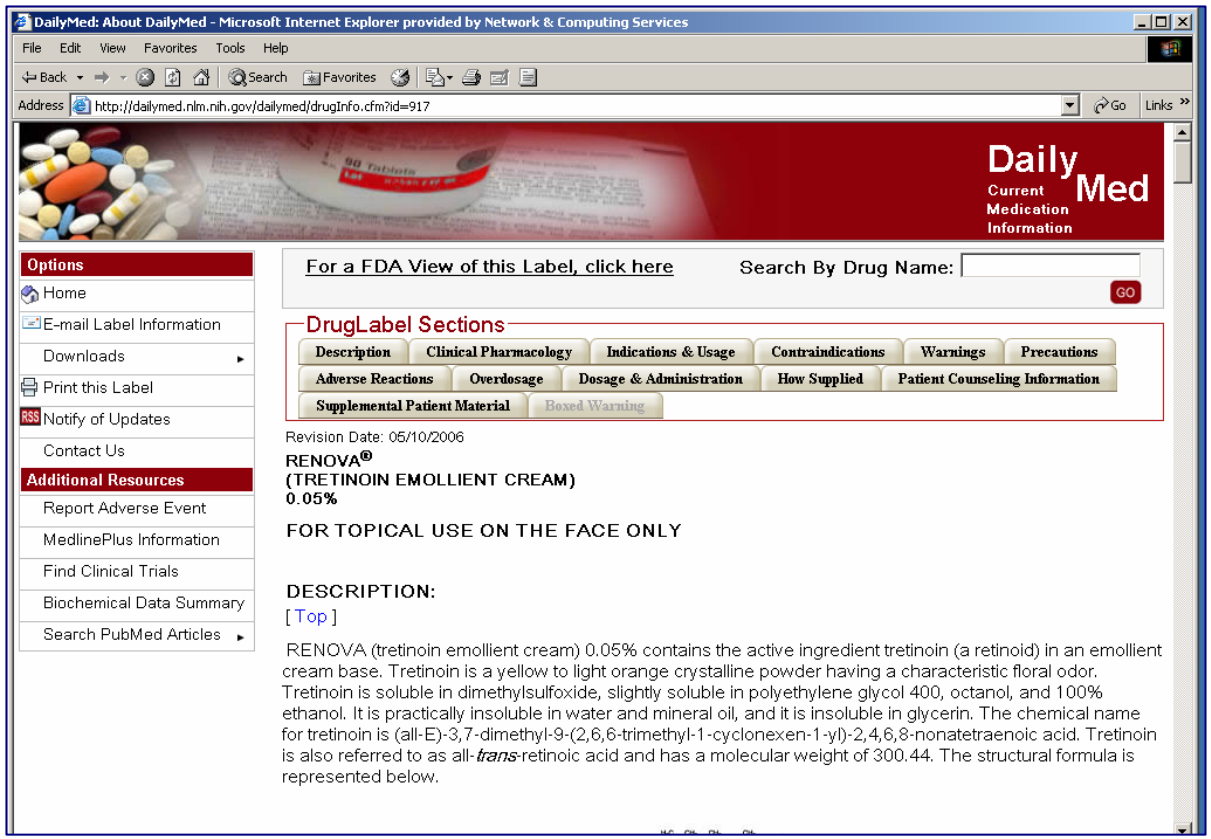

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