Quick Reference Guide & Checklist for FDA Regulatory UDI Requirements § 801.20:

As outlined by the FDA the following are the requirements for UDI medical device labelling of all classes of medical device (requirement as of September 2013).

Device Identifier:

Content:	**Completed:**
Labeller information	
Specific model/version information	

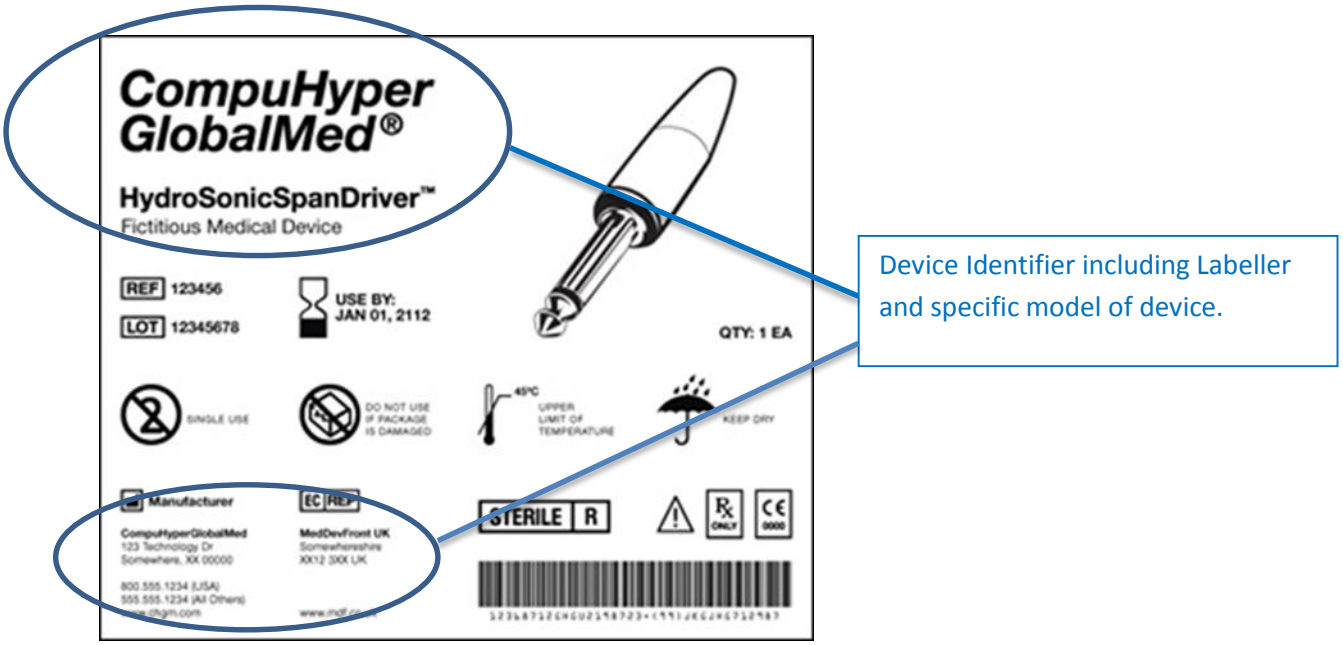

Fig 1: Fictitious example 1 of a medical device UID label illustrating DI as proposed by the FDA**:**

Product Identifier:

Content:	**Completed:**
Lot or batch number within which a device was manufactured	
Serial number of specific device	
Expiry date of specific device	
Date of manufacture	
Distinct Identification Code as required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based products (HCT/P) regulated as a medical device	

Fig 2: Fictitious example of a medical device UID label illustrating Product Identifier as proposed by the FDA

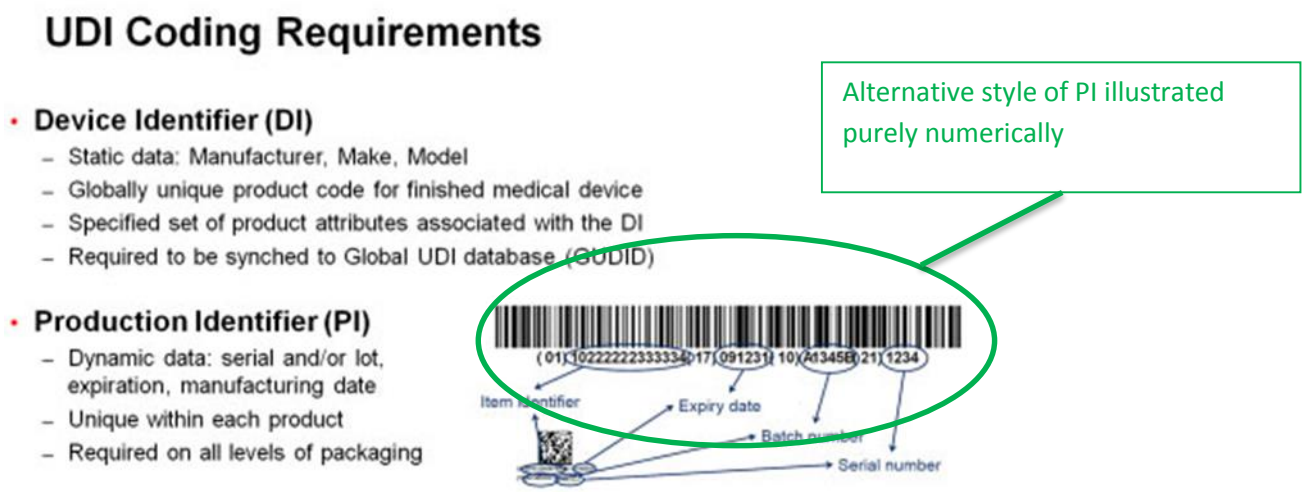

Fig 3: Alternative example of UDI illustrating DI and PI requirements in order to comply with new FDA UDI regulations

GUDID Submission:

Medical device:	Accrediting Agency:	Submission Date