DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

IMDRF International Medical Device Regulators Forum

IMDRF/DITTA Joint Virtual Workshop

9 Sept. 2021

OSSTEM Implant UDI Application System and Suggestions for Application of UDI by Countries.

Hee-kwon Son

OSSTEM IMPLANT Co., Ltd.

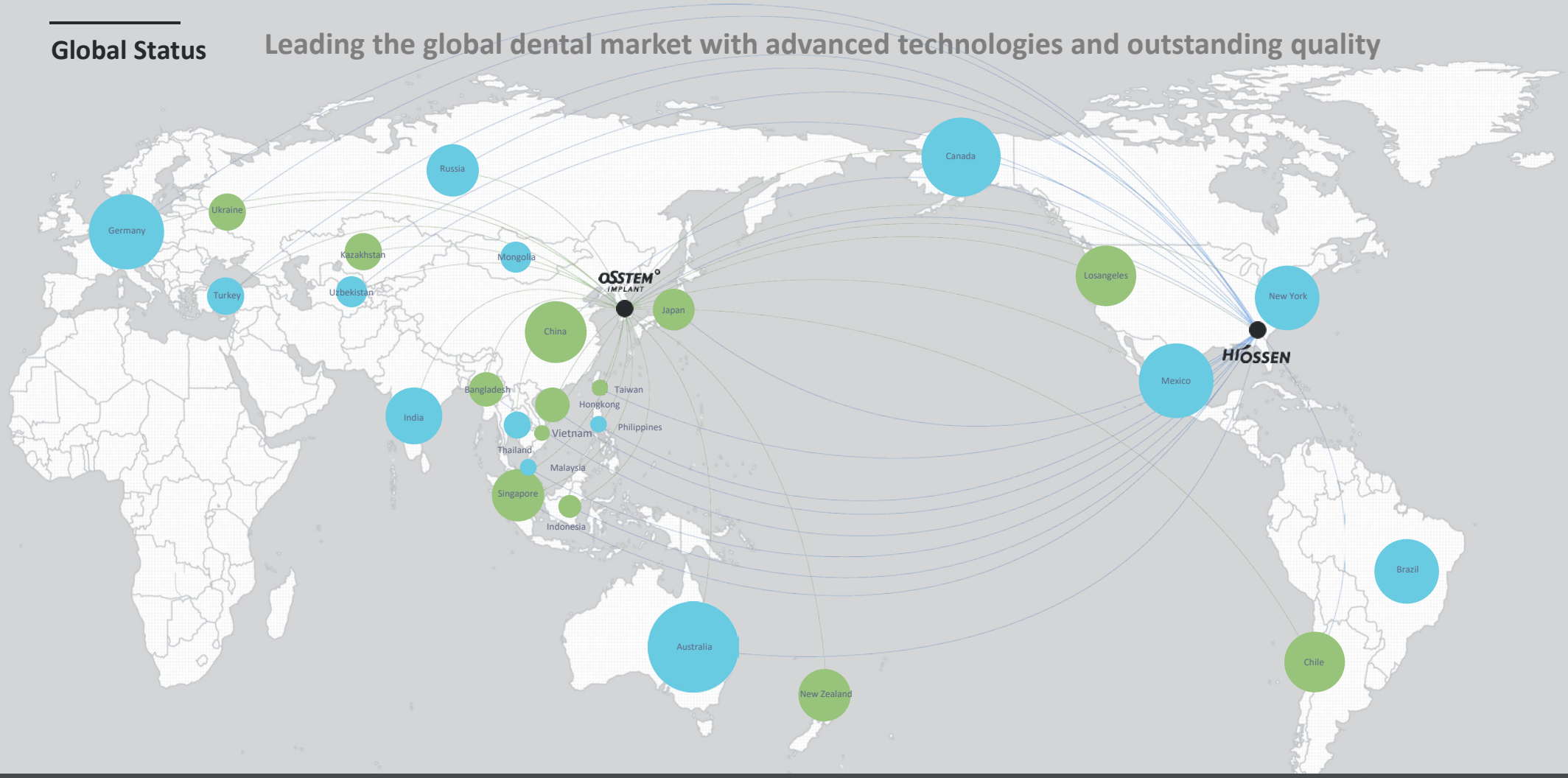
OSSTEM IMPLANT Co., Ltd.

Company name	OSSTEM IMPLANT CO., LTD.
CEO	TAE KWAN EOM
Date of Incorporation	January 8, 1997
Headquarter	3, Magokjungang 12-ro, Gangseo-gu, Seoul, Korea
Subsidiaries	· Operates Philadelphia production subsidiary in U.S · Operates a total of 29 subsidiaries in 27 countries · Operates 9 domestic subsidiaries
Capital	USD 6.2 million*
Sales	USD 551 million* (2020)
Website	www.osstem.com
Business	Production and sales of dental implant materials and medical equipment, development and sales of related software

* Based on exchange rates as of July 9, 2021(1$=1,149.10 won)

Global Status

Leading the global dental market with advanced technologies and outstanding quality



Our branches around the world

Operates a total of 29 branches in 25 countries

Operates Philadelphia production branch in the U.S.

Status in the global market

Exports products to more than 70 countries around the world

First in the Asian/Pacific market, fourth in the global market

OSSTEM IMPLANT Product Line

OSSTEM Implant Provide total solutions in dental cares

Implant

Dental Implant
Abutment
Surgical tool

Dental equipment

Dental Unit chair
Composite imaging equipment
Digital panorama
X-ray

Dental materials And GBR

Bone material
Membrane
Impression material
Dental Orthodontic

Dental IT

Dental Interior

Education

OSSTEM implant has and Manage a variety of dental products with over 30,000 model numbers (References)

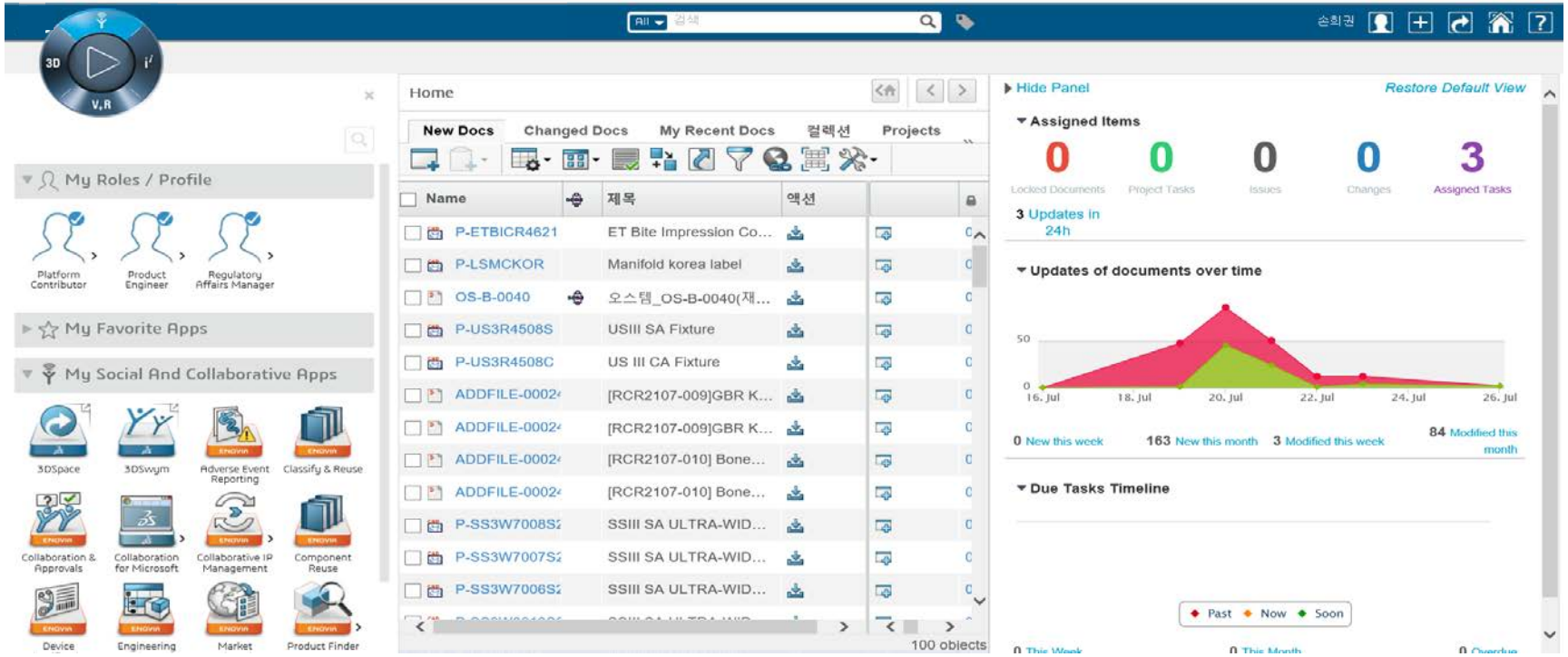
Accordingly , System to properly manage references with medical device regulations and standards including UDI information is required

Computerized Medical Device Management

PLM System

Product **L**ifecycle **M**anagement

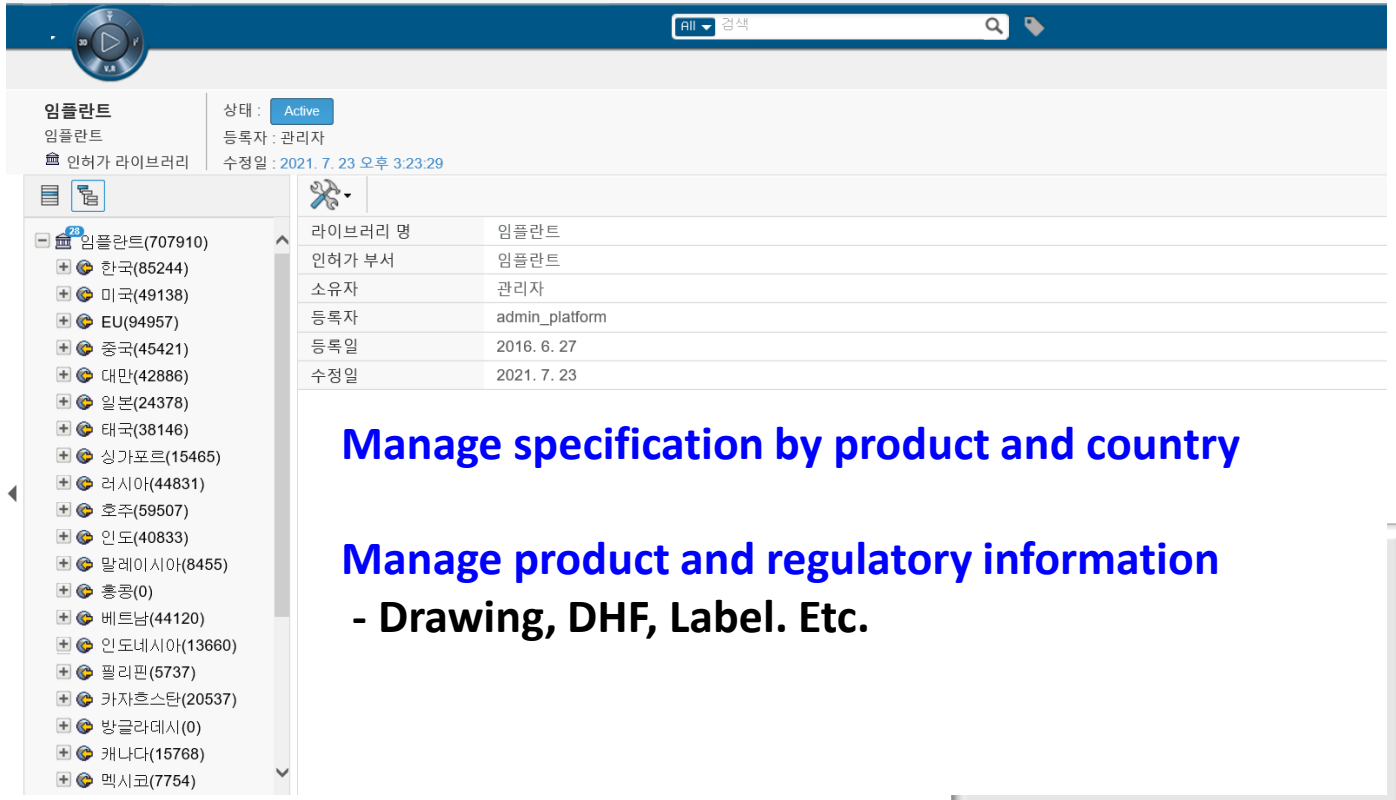
A production system that increases the product added value but reduces costs by consistently managing the entire process from design to final production



Manage UDI information of the product's each reference by applying PLM and SAP production system

OSSTEM PLM System

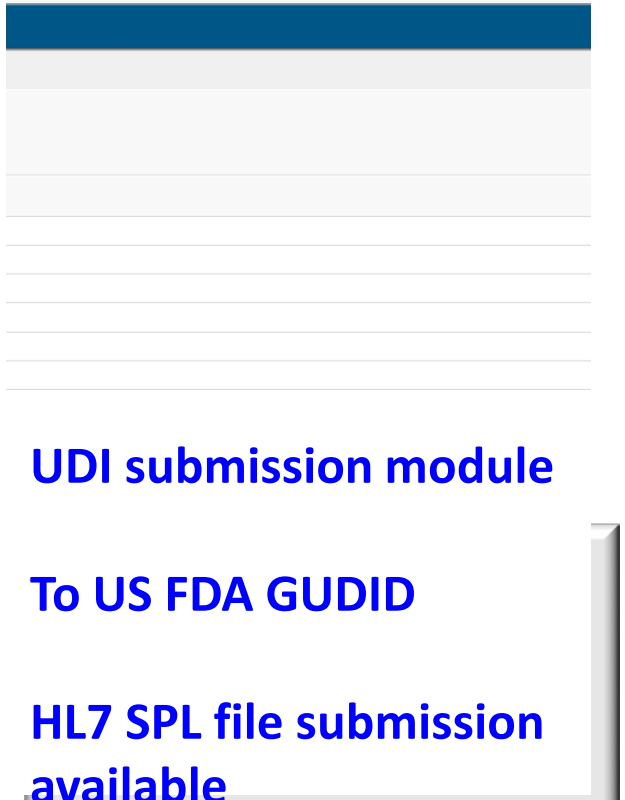
Specification management for over 22 different countries



Manage specification by product and country

Manage product and regulatory information
- **Drawing, DHF, Label. Etc.**

FDA GUDID submission module



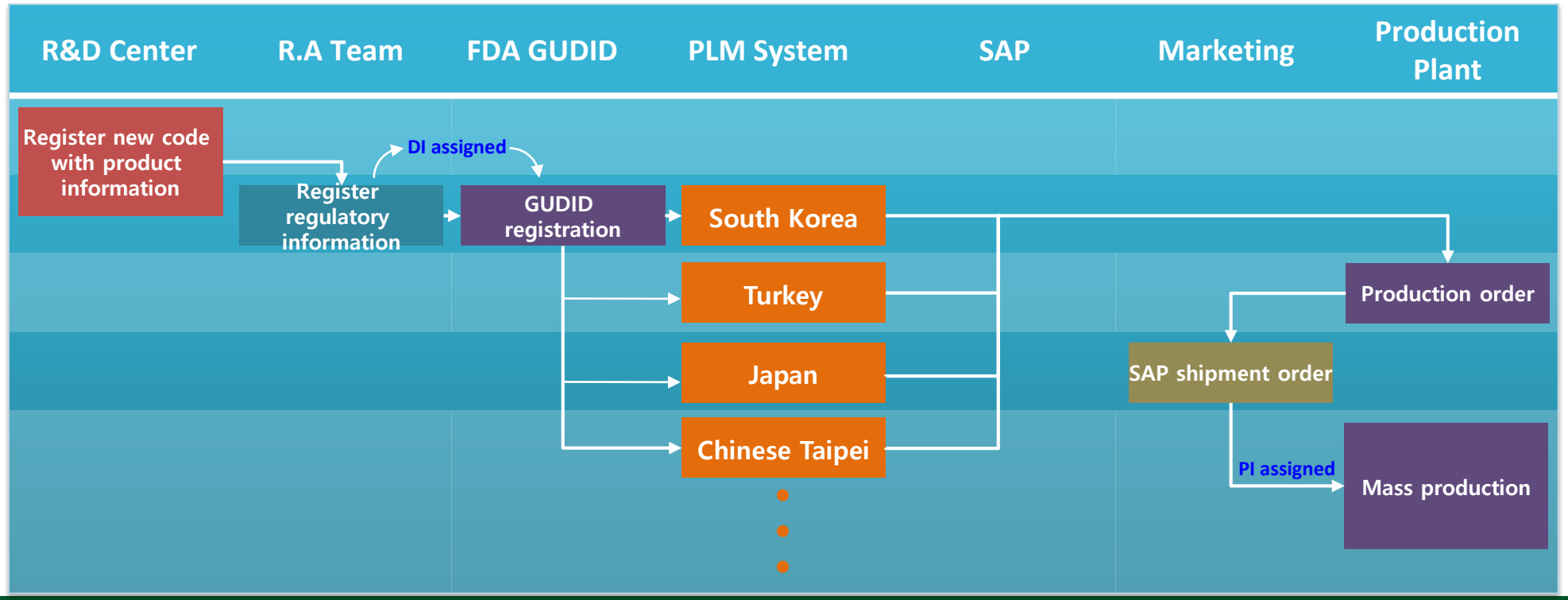
UDI submission module

To US FDA GUDID

HL7 SPL file submission available

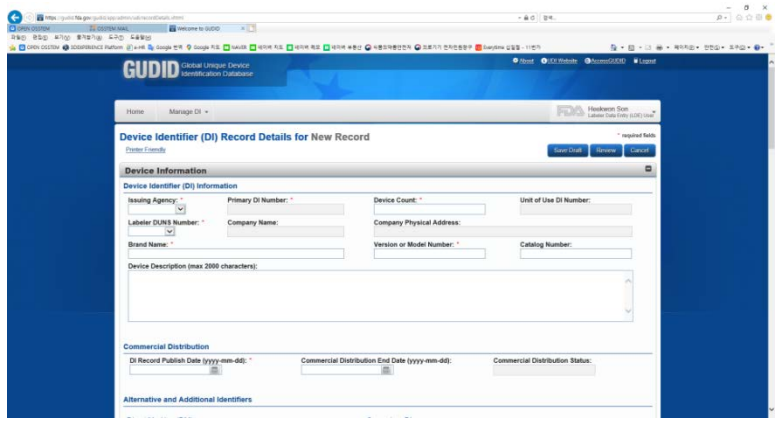
OSSTEM Computerized Data Processing

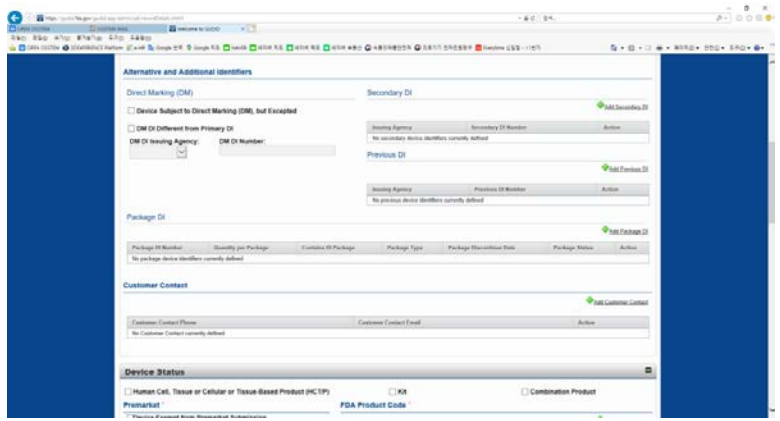
- Integrated management of design change, QC management, and UDI submission via PLM system
- Possible to efficient industrial regulatory level management in global market
- Possible to minimize time to market and to efficient regulatory management with one COMPREHENSIVE system

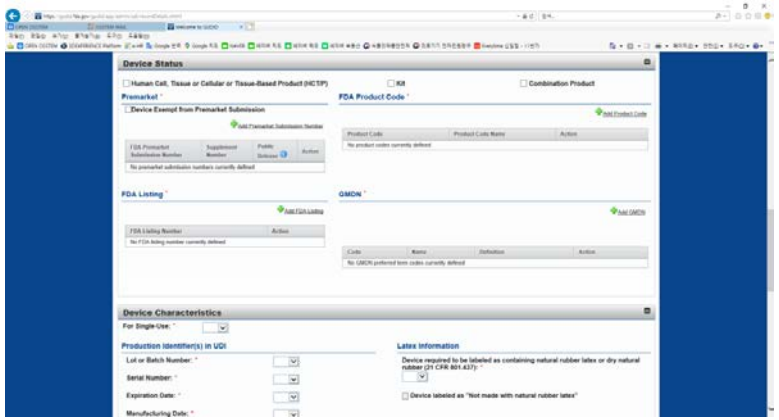


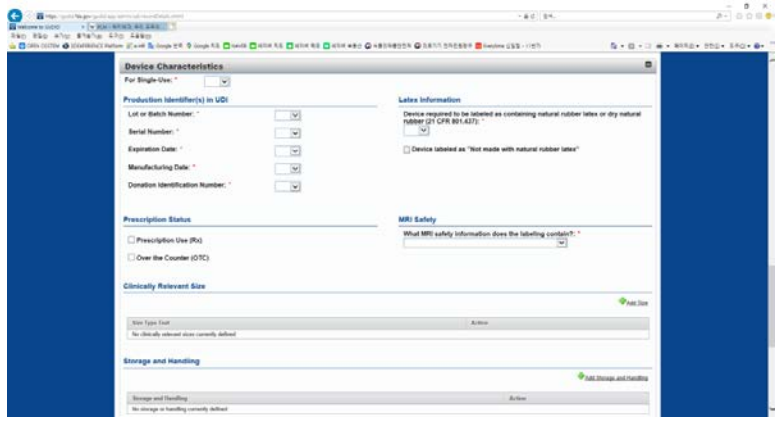
FDA GUDID System

- In the case of FDA GUDID system, more than 37 device information registrations including the information of issuing agency are required
- Manual data entry (submitting single DI records manually) using the GUDID web application as well as HL7 SPL file submission (submitting many DI records) using FDA electronic submissions gateway







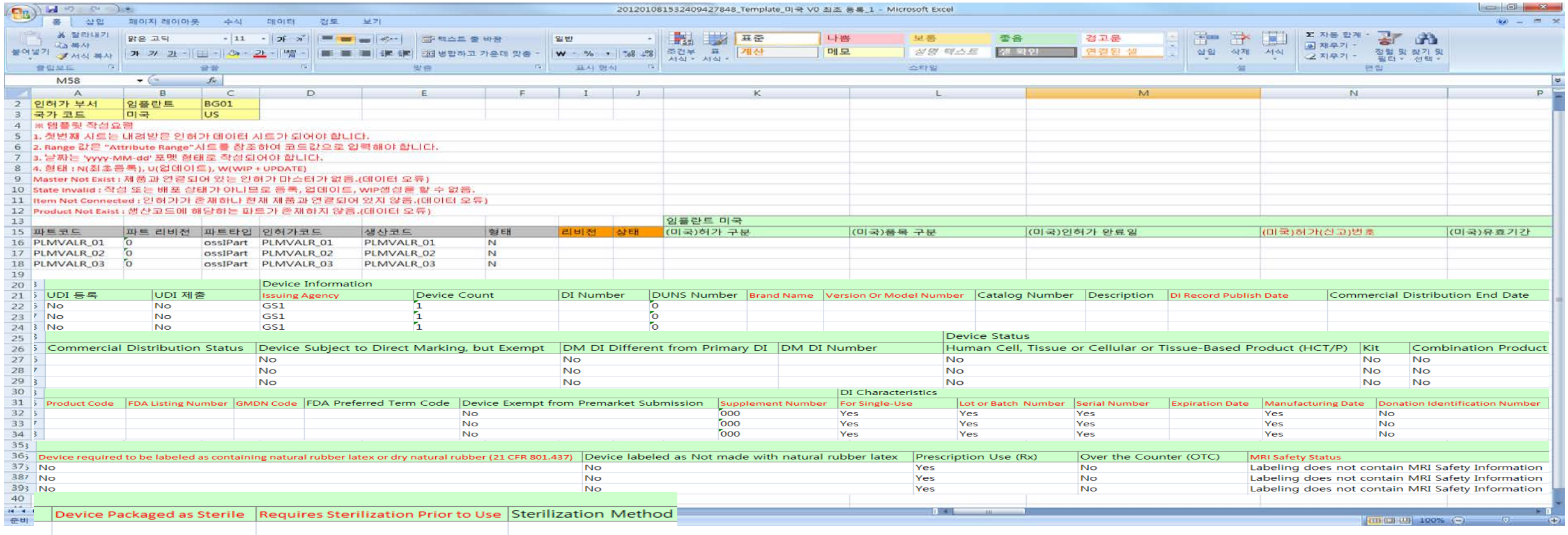


https://gudid.fda.gov/gudid/

FDA GUDID System

In the case of OSSTEM Implant which owns various reference, HL7 SPL file submission is set up which allows bulk submission at once

Download the references for UDI submission in the file format below from PLM system and fill in the necessary information



인허가 부서	임플란트	BG01
국가 코드	미국	US

※ 템플릿 작성요령
1. 첫번째 시트는 내려받은 인허가 데이터 시트가 되어야 합니다.
2. Range 값은 "Attribute Range"시트를 참조하여 코드값으로 입력해야 합니다.
3. 날짜는 'yyyy-MM-dd' 포멧 형태로 작성되어야 합니다.
4. 형태 : N(최초등록), U(업데이트), W(WIP + UPDATE)
Master Not Exist : 제품과 연결되어 있는 인허가 마스터가 없음.(데이터 오류)
State invalid : 작성 또는 배포 상태가 아니므로 등록, 업데이트, WIP생성을 할 수 없음.
Item Not Connected : 인허가가 존재하나 현재 제품과 연결되어 있지 않음.(데이터 오류)
Product Not Exist : 생산코드에 해당하는 파트가 존재하지 않음.(데이터 오류)

								임플란트 미국				
파트코드	파트 리비전	파트타입	인허가코드	생산코드	형태	리비전	상태	(미국)허가 구분	(미국)등록 구분	(미국)인허가 완료일	(미국)허가(신고)번호	(미국)유효기간
PLMVALR_01	0	ossIPart	PLMVALR_01	PLMVALR_01	N							
PLMVALR_02	0	ossIPart	PLMVALR_02	PLMVALR_02	N							
PLMVALR_03	0	ossIPart	PLMVALR_03	PLMVALR_03	N							

		Device Information									
UDI 등록	UDI 제출	Issuing Agency	Device Count	DI Number	DUNS Number	Brand Name	Version Or Model Number	Catalog Number	Description	DI Record Publish Date	Commercial Distribution End Date
No	No	GS1	1		0						
No	No	GS1	1		0						
No	No	GS1	1		0						

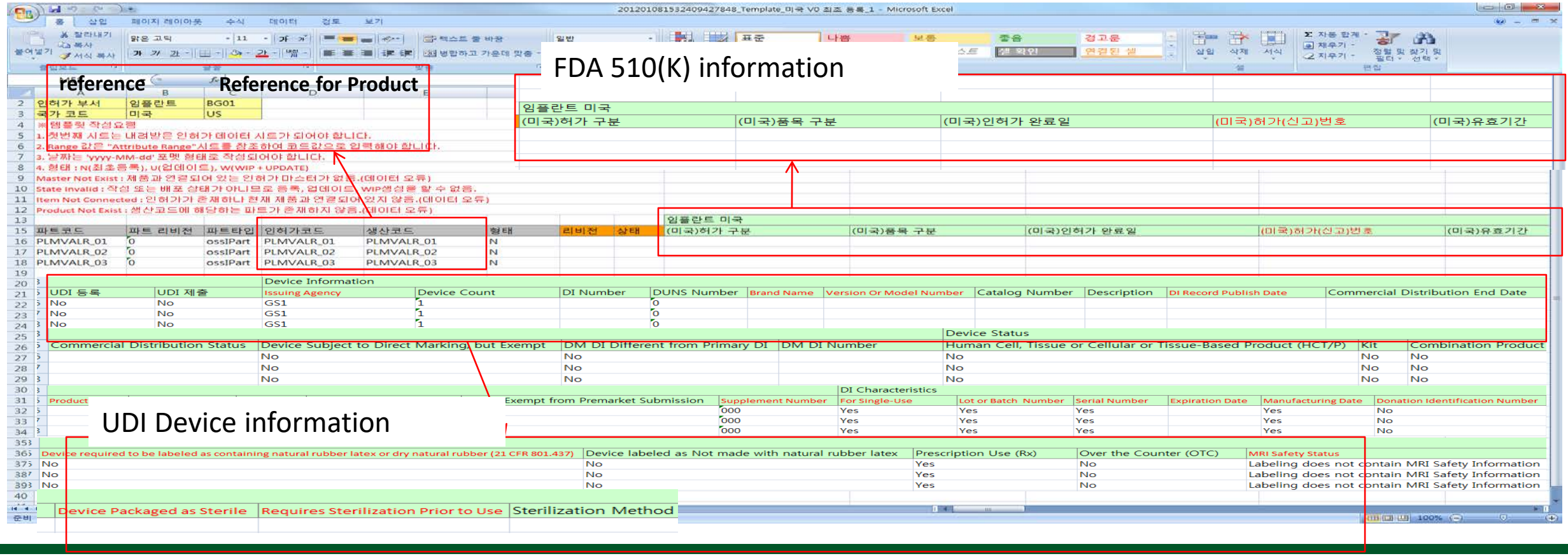
			Device Status			
Commercial Distribution Status	Device Subject to Direct Marking, but Exempt	DM DI Different from Primary DI	DM DI Number	Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)	Kit	Combination Product
	No	No		No	No	No
	No	No		No	No	No
	No	No		No	No	No

						DI Characteristics					
Product Code	FDA Listing Number	GMDN Code	FDA Preferred Term Code	Device Exempt from Premarket Submission	Supplement Number	For Single-Use	Lot or Batch Number	Serial Number	Expiration Date	Manufacturing Date	Donation Identification Number
				No	000	Yes	Yes	Yes		Yes	No
				No	000	Yes	Yes	Yes		Yes	No
				No	000	Yes	Yes	Yes		Yes	No

Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)	Device labeled as Not made with natural rubber latex	Prescription Use (Rx)	Over the Counter (OTC)	MRI Safety Status
No	No	Yes	No	Labeling does not contain MRI Safety Information
No	No	Yes	No	Labeling does not contain MRI Safety Information
No	No	Yes	No	Labeling does not contain MRI Safety Information

Device Packaged as Sterile	Requires Sterilization Prior to Use	Sterilization Method

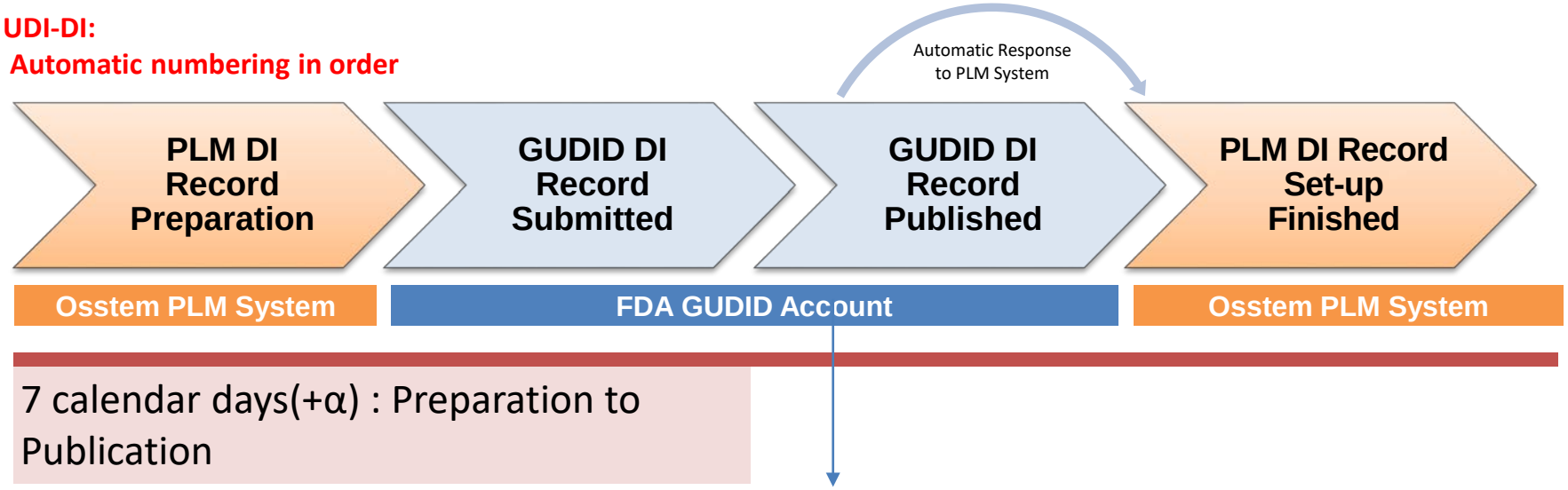
FDA GUDID System



FDA GUDID Registration Process

Set up the UDI Record via FDA GUDID Registration System which first introduced this UDI system to the world, and apply this same published UDI to all countries.

UDI-DI:
Automatic numbering in order



7 calendar days(+α) : Preparation to Publication

❖Editing Limitation determined by the

❖Grace Period

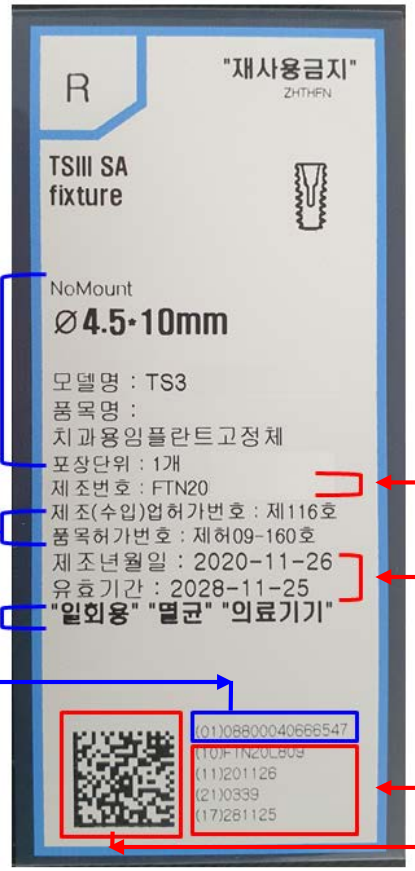
- Grace Period is 7 calendar days and starts the day after the DI record is published (edited all attributes, except Publish Date)

Example of PLM & SAP Labeling Application

PLM

Development/Regulatory information

Device basic information
Device name
Item name
Package unit
Registration number
Required/essential information
UDI-DI number(assigned automatically)



SAP

Production information

Manufacturing date
Expiration date
UDI-PI (based on production data of the device)
Barcode generation

US FDA UDI Device Information

US UDI Device information list

PLM	Input example
(US)Regulatory status	OINST030
(US)Item classification	INHPS001
(US)Registration date	2016-10-17
(US)PMA(PMN) number	K161604
(US)Expiration date	VD4
Issuing Agency	GS1
Device Count	1
DI Number	08800000963761
DUNS Number	689051793
Brand Name	OSSTEM IMPLANT SYSTEM
Version Or Model Number	BTS3S4010S
Catalog Number	
Description	
DI Record Publish Date	2017-04-06
Commercial Distribution End Date	

PLM	Input example
Commercial Distribution Status	
Device Subject to Direct Marking, but Exempt	No
DM DI Different from Primary DI	No
DM DI Number	
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)	No
Kit	No
Combination Product	No
Product Code	DZE
FDA Listing Number	D276938
GMDN Code	55849
FDA Preferred Term Code	
Device Exempt from Premarket Submission	No
Supplement Number	000
For Single-Use	Yes
Lot or Batch Number	Yes

PLM	Input example
Serial Number	Yes
Expiration Date	Yes
Manufacturing Date	Yes
Donation Identification Number	No
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)	No
Device labeled as Not made with natural rubber latex	No
Prescription Use (Rx)	No
Over the Counter (OTC)	No
MRI Safety Status	Labeling does not contain MRI Safety Information
Device Packaged as Sterile	Yes
Requires Sterilization Prior to Use	No
Sterilization Method	

South Korea KFDA UDI Device Information

South Korea UDI Device information list : Register at South Korea Medical Device Unified Information System (Allows bulk submission at the system; no linkage to PLM system)

Unified Information System	Explanation
Item serial number	Automatic entry of regulatory information
Model serial number	Automatic entry of regulatory information
Number	Automatic entry of regulatory information
Item number	Automatic entry of regulatory information
Class	Automatic entry of regulatory information
Manufacture/Import	Automatic entry of regulatory information
Registration number	Automatic entry of regulatory information
Registration date	Automatic entry of regulatory information
Model number	Automatic entry of regulatory information
Issuing Agency	Entry selection (GS1, HIBBCC, ICCBBA)
Device Identifier(UDI-DI)	08800000982809
Lot number	Entry selection (Y or N)
Serial number	Entry selection (Y or N)
Manufacturing date	Entry selection (Y or N)
Expiration date	Entry selection (Y or N)
Sterilization	Entry selection (Y or N)
Package unit	Manual entry
Latex	Entry selection (Y or N)

Unified Information System	Explanation
Phthalates	Entry selection (Y or N)
MRI safety status	Entry selection (safe, unsafe etc.)
Storage condition	Manual entry
Distribution, handling condition	Manual entry
Version	Manual entry
Remark (Warn, caution or contraindication)	Manual entry
Additional information	Manual entry
Chief manager contact	Manual entry
Chief manager e-mail	Manual entry
Customer Service name	Manual entry
Customer Service contact	Manual entry
Require sterilization prior to use	Entry selection (Y or N)
Sterilization method1	Entry selection (Steam, gamma etc.)
Sterilization method1_other	Manual entry
Sterilization method2	Entry selection (Steam, gamma etc.)
Sterilization method2_other	Manual entry
Sterilization method3	Entry selection (Steam, gamma etc.)

Unified Information System	Explanation
Sterilization method3_other	Manual entry
Benefit claim	Manual entry
Benefit claim code1	Manual entry
Benefit claim code2	Manual entry
Benefit claim code3	Manual entry
Benefit claim code4	Manual entry
Benefit claim code5	Manual entry
Benefit claim code Reason for not entering	Manual entry
Secondary logistics barcode	Manual entry
Unit in secondary package	Manual entry
Tertiary logistics barcode	Manual entry
Unit in tertiary package	Manual entry
4^{th} logistics barcode	Manual entry
Unit in 4^{th} package	Manual entry

Comparison of Information used in Common (FDA Vs MFDS)

For UDI device information of the same product, only 11 types of common information can be used. If common information is used by designating with the same standard/rule, it is expected that both registrants and users can increase the information utilization.

No.	US FDA GUDID	South Korea Unified Information System
1	Issuing Agency	코드체계
2	DI Number	고유식별자(UDI-DI) 코드
3	Lot or Batch Number	로트번호
4	Serial Number	일련번호
5	Expiration Date	사용기한
6	Manufacturing Date	제조연월
7	Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)	라텍스 포함
8	MRI Safety Status	MRI 안전노출 여부
9	Device Packaged as Sterile	멸균의료기기
10	Requires Sterilization Prior to Use	사용 전 멸균 필요
11	Sterilization Method	멸균방법

UDI Application by Countries

Country	Compliance data	Remark
South Korea	Currently in effect (Completion of compliance to Class II) Class IV : 2019.07.01~ Class III : 2020.07.01~ Class II : 2021.07.01~ Class I : 2022.07.01~	
United States	Currently in effect (Completion of compliance to Class II) Class I : 2022.09.24~	
European Union(CE)	(New products applied of MDR) Class III : 2021.05.26~ Class IIb/IIa : 2023.05.26~ Class I : 2025.05.26~	No UDI obligations to MDD products

UDI Application by Countries

Country	Compliance data	Remark
Singapore	2022 - Applied to the high-risk implantable medical devices such as coronary artery stents, orthopedic joint implants, and implantable contact lens 2024 - All other Class D medical devices 2026 - All Class C medical devices 2028 - All Class B medical devices	
Turkey	In effect on 2018 Allow market the CE-approved products only registered in UTS (Product Tracking System) with UDI information.	
Japan	Not mandatory, but voluntarily participate in applied of UDI regulations Used for E-Labeling application	

Suggestions for Application of UDI by Countries

Item	Suggestion	Description
Development of UDI information submission linkage system	Require a system capable of mass submission and management of UDI information of multi-product product line	Apply a method that can be submitted in conjunction with management programs such as PLM and SAP to US FDA HL7 SPL file
Unification of UDI information by countries	Harmonize UDI device information through international standardization	Unify the UDI submission information by countries and use the same UDI information to register and check the same information in all countries
Simplification of labeling information	Operate web-based information system by application of UDI and E-Labeling system	Activate the E-Labeling system in order to minimize the contents of the label through the use of UDI information (difficult to contain various information of small devices due to its insufficient label size)

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Thank you!