



**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<sup>®</sup>

## IMPLANT

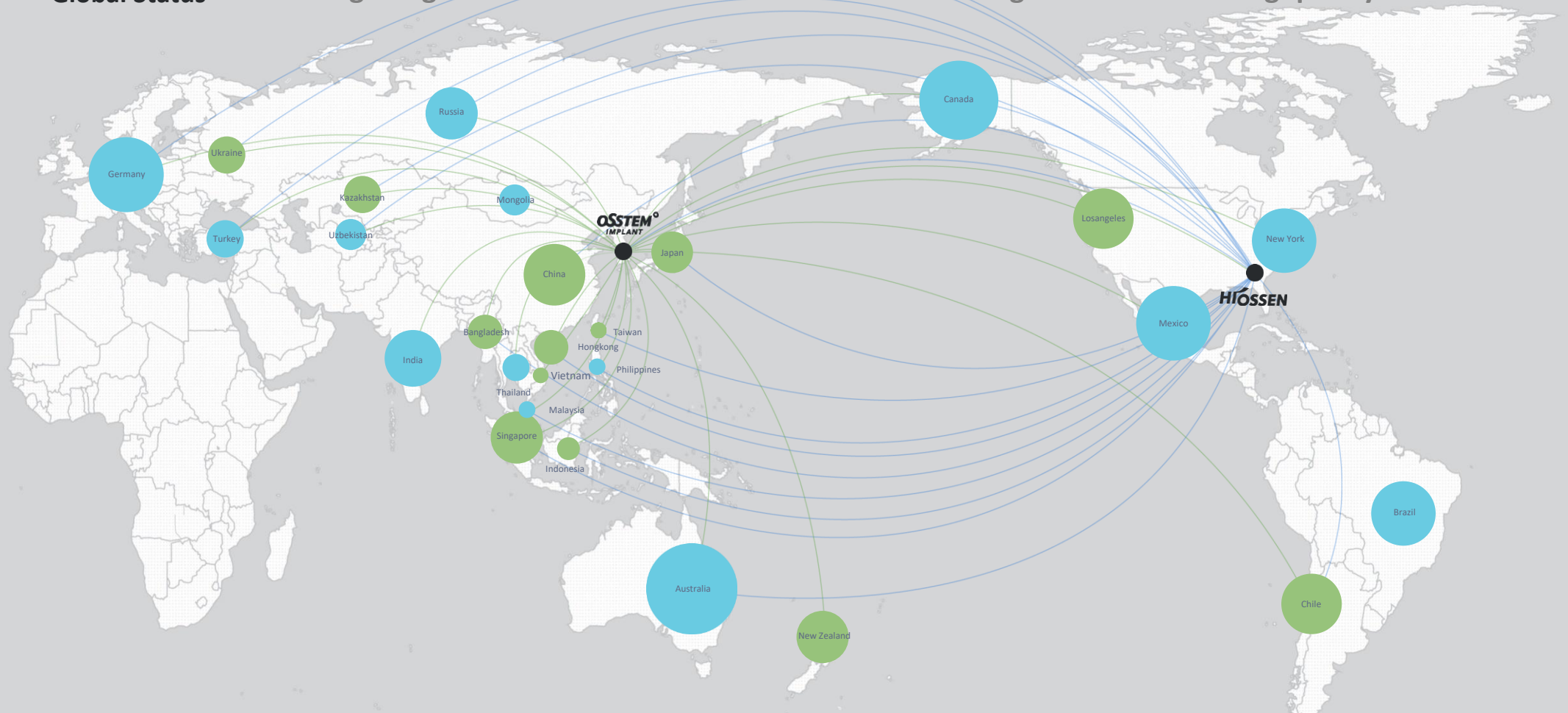


Company name	OSSTEM IMPLANT CO., LTD.
CEO	TAE KWAN EOM
Date of Incorporation	January 8, 1997
Headquarter	3, Magokjungang 12-ro, Gangseo-gu, Seoul, Korea
Subsidiaries	<ul style="list-style-type: none"> <li>• Operates Philadelphia production subsidiary in U.S</li> <li>• Operates a total of 29 subsidiaries in 27 countries</li> <li>• Operates 9 domestic subsidiaries</li> </ul>
Capital	USD 6.2 million*
Sales	USD 551 million* (2020)
Website	<a href="http://www.osstem.com">www.osstem.com</a>
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

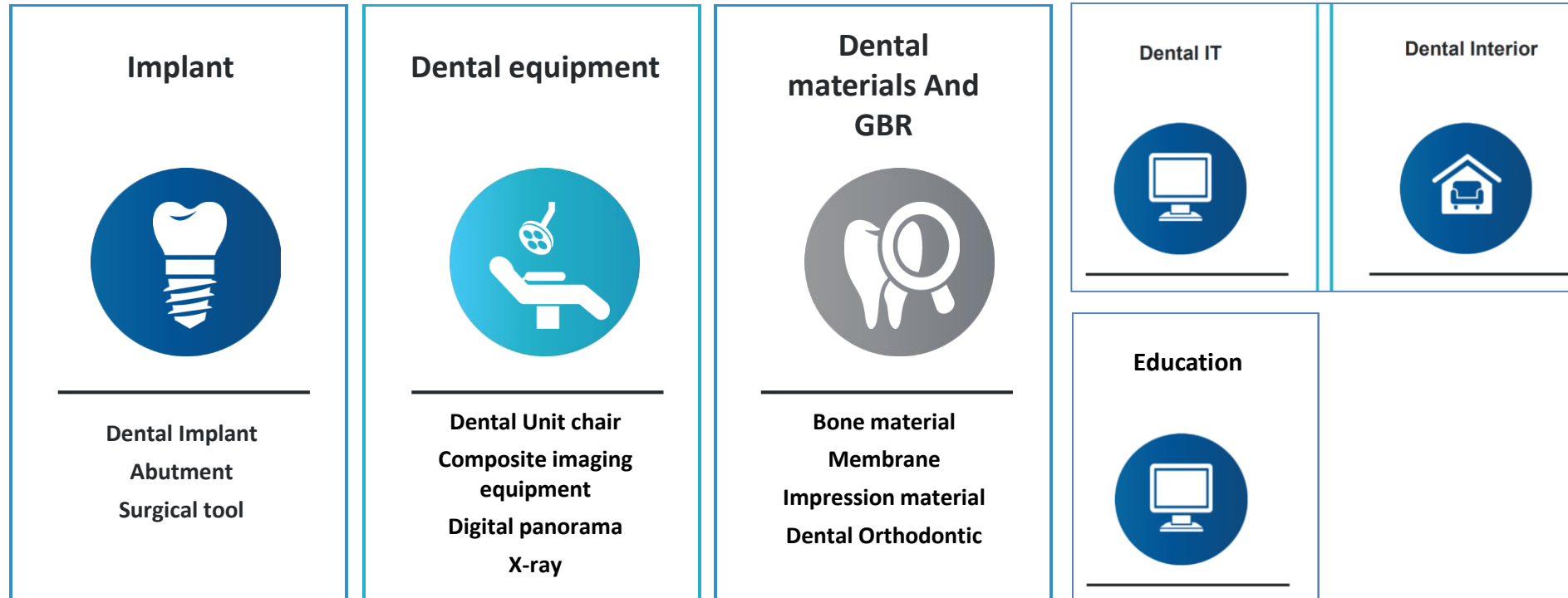
Operates a total of 29 branches in 25 countries  
Operates Philadelphia production branch in the U.S.



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 Provide total solutions in dental cares



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

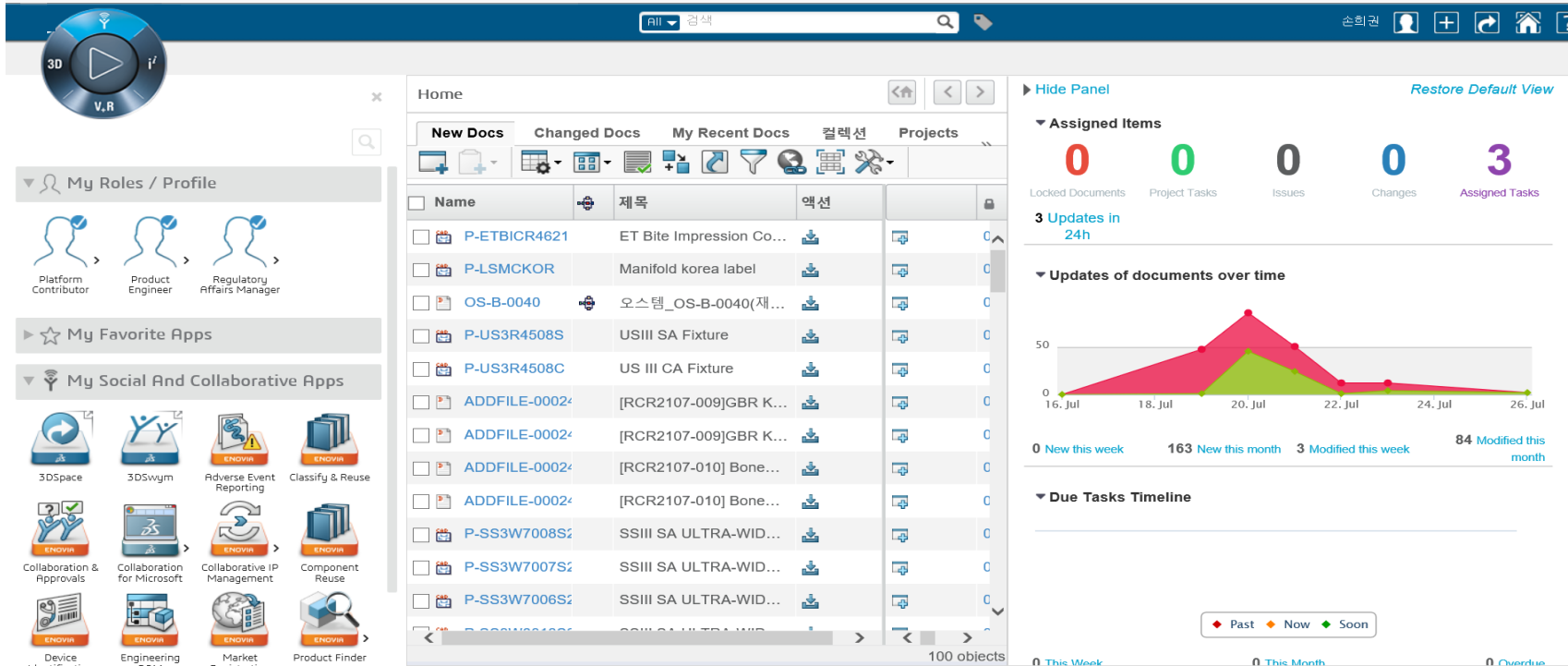
Accordingly , System to properly manage references with medical device regulations and standards including UDI information is required

# Computerized Medical Device Management

## PLM System

### Product Lifecycle Management

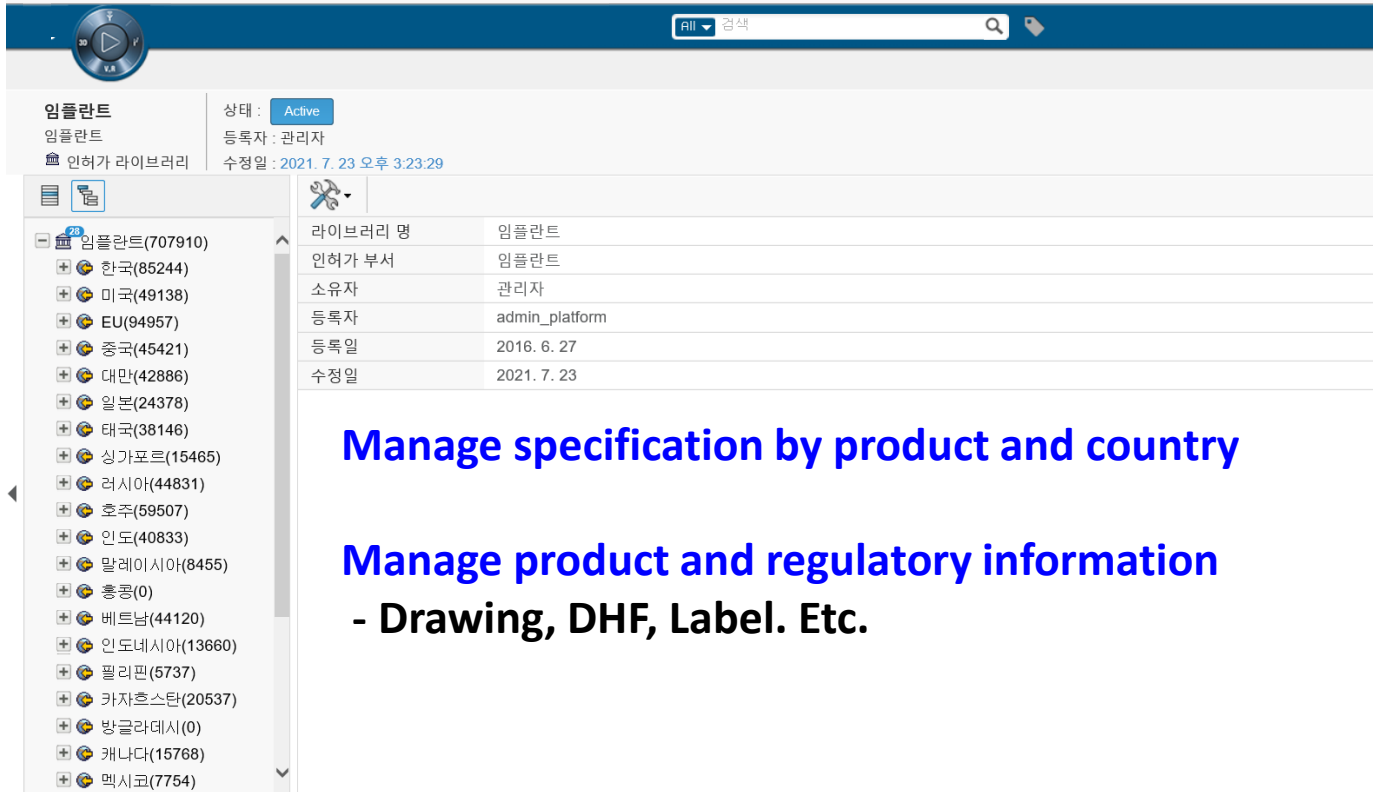
A production system that increases the product added value but reduces costs by consistently managing the entire process from design to final production



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



## Specification management for over 22 different countries



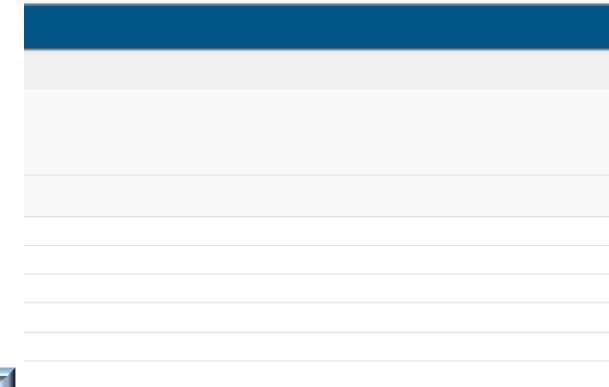
The screenshot displays the OSSTEM PLM System interface. On the left, a sidebar lists countries with their respective counts: 한국(85244), 미국(49138), EU(94957), 중국(45421), 대만(42886), 일본(24378), 태국(38146), 싱가포르(15465), 러시아(44831), 호주(59507), 인도(40833), 말레이시아(8455), 홍콩(0), 베트남(44120), 인도네시아(13660), 필리핀(5737), 카자흐스탄(20537), 방글라데시(0), 캐나다(15768), and 멕시코(7754). The main area shows details for a selected product (임플란트) with fields for registration number, status (Active), and registration date. A table lists regulatory information for different countries, including registration numbers and dates.

라이브러리 명	임플란트
인허가 부서	임플란트
소유자	관리자
등록자	admin_platform
등록일	2016. 6. 27
수정일	2021. 7. 23

**Manage specification by product and country**

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

## FDA GUDID submission module



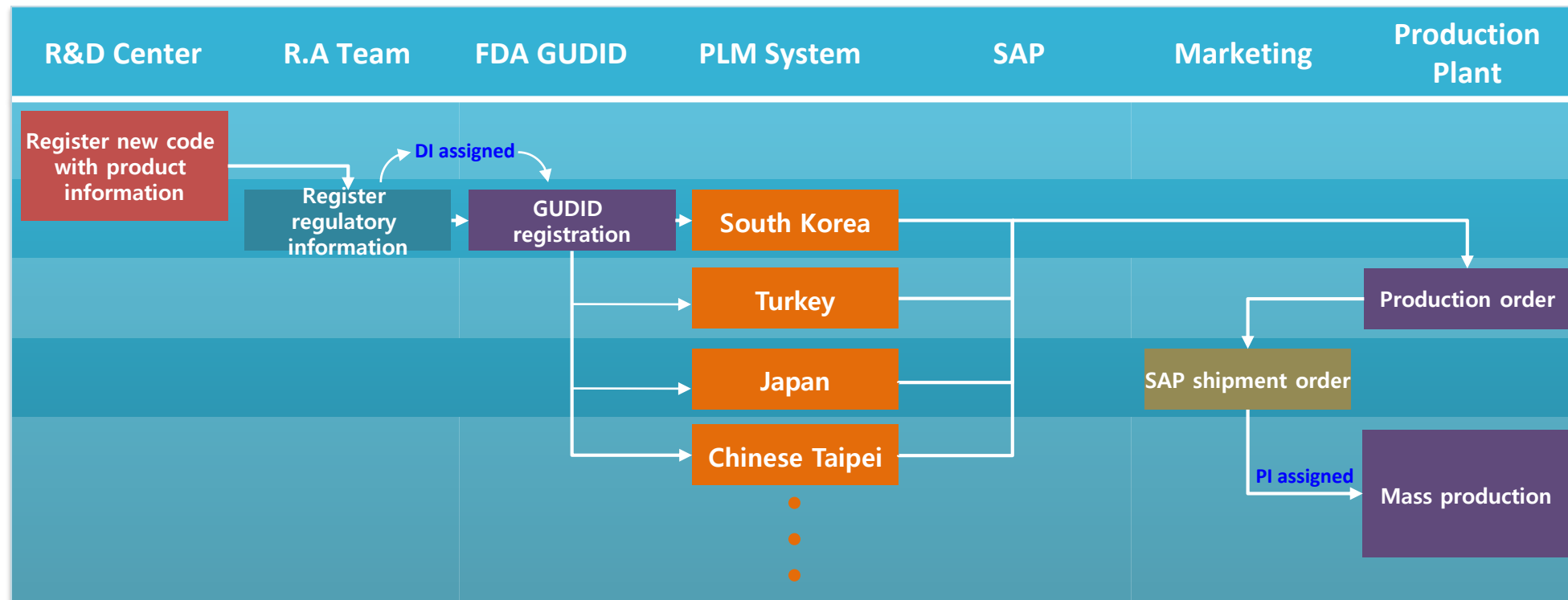
**UDI submission module**

**To US FDA GUDID**

**HL7 SPL file submission**  
**available**

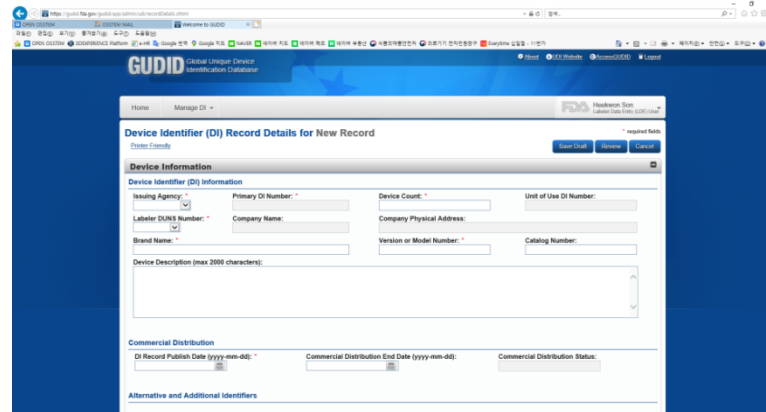
# OSSTEM Computerized Data Processing

- 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



**GUDID Global Unique Device Identification Database**

Home Manage DI +

**Device Identifier (DI) Record Details for New Record**

Device Information

Issuing Agency: [Select] Primary DI Number: [Text] Device Count: [Text] Unit of Use DI Number: [Text]

Labeler DUNS Number: [Text] Company Name: [Text] Company Physical Address: [Text]

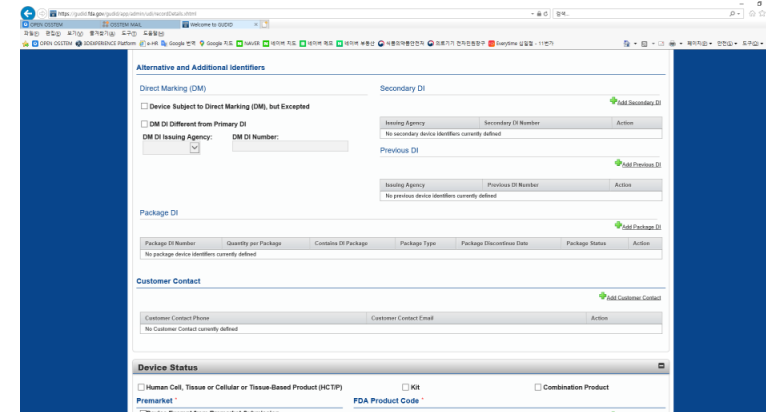
Brand Name: [Text] Version or Model Number: [Text] Catalog Number: [Text]

Device Description (max 2000 characters): [Text Area]

Commercial Distribution

DI Record Publish Date (yyyy-mm-dd): [Text] Commercial Distribution End Date (yyyy-mm-dd): [Text] Commercial Distribution Status: [Text]

Alternative and Additional Identifiers



**Alternative and Additional Identifiers**

Direct Marking (DM)

☐ Device Subject to Direct Marking (DM), but Excepted

☐ DM DI Different from Primary DI

DM DI Issuing Agency: [Text] DM DI Number: [Text]

Secondary DI

Issuing Agency: [Text] Secondary DI Number: [Text] Action: [Text]

No secondary device identifiers currently defined

Previous DI

Issuing Agency: [Text] Previous DI Number: [Text] Action: [Text]

No previous device identifiers currently defined

Package DI

Package DI Number: [Text] Quantity per Package: [Text] Contains DI Package: [Text] Package Type: [Text] Package Distribution Date: [Text] Package Status: [Text] Action: [Text]

No package device identifiers currently defined

Customer Contact

Customer Contact Phone: [Text] Customer Contact Email: [Text] Action: [Text]

No Customer Contact currently defined

Device Status

☐ Human Cell, Tissue or Cellular or Tissue-Based Product (HCTBP) ☐ Kit ☐ Combination Product

Premarket ☐ FDA Product Code

☐ Device Exempt from Premarket Submission

Product Code: [Text] Product Code Name: [Text] Action: [Text]

No product codes currently defined

FDA Listing

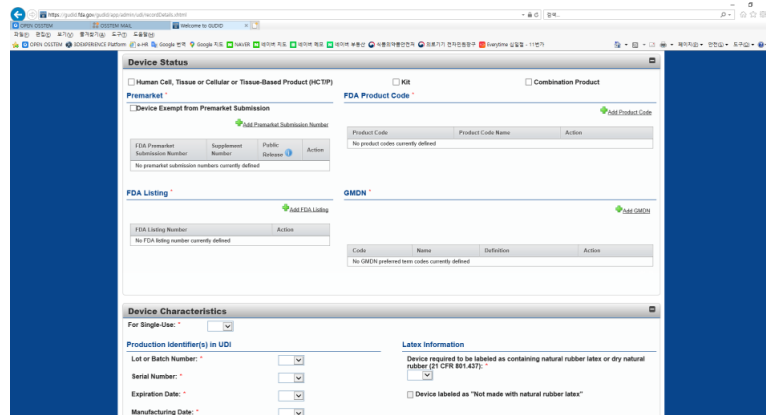
FDA Listing Number: [Text] Action: [Text]

No FDA listing number currently defined

GMGN

Code: [Text] Name: [Text] Definition: [Text] Action: [Text]

No GUDID preferred term codes currently defined



**Device Status**

☐ Human Cell, Tissue or Cellular or Tissue-Based Product (HCTBP) ☐ Kit ☐ Combination Product

Premarket ☐ FDA Product Code

☐ Device Exempt from Premarket Submission

Product Code: [Text] Product Code Name: [Text] Action: [Text]

No product codes currently defined

FDA Listing

FDA Listing Number: [Text] Action: [Text]

No FDA listing number currently defined

GMGN

Code: [Text] Name: [Text] Definition: [Text] Action: [Text]

No GUDID preferred term codes currently defined

**Device Characteristics**

For Single-Use: ☐

Production Identifier(s) in UDI

Lot or Batch Number: [Text] [Add]

Serial Number: [Text] [Add]

Expiration Date: [Text] [Add]

Manufacturing Date: [Text] [Add]

Latex Information

Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 891.437): ☐

☐ Device labeled as "Not made with natural rubber latex"

Prescription Status

☐ Prescription Use (Rx) ☐ Over the Counter (OTC)

Clinically Relevant Size

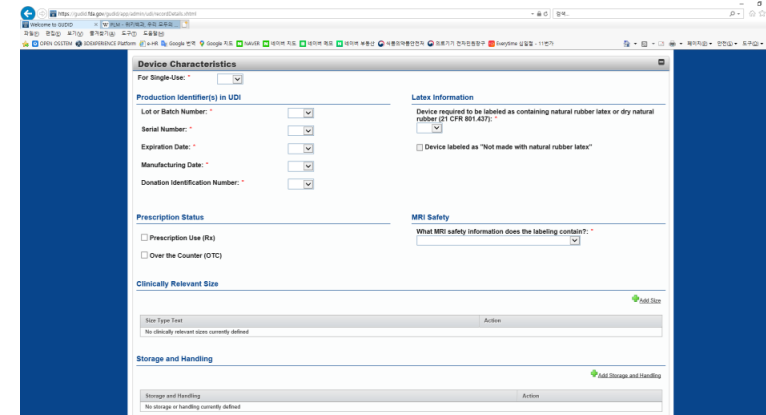
Size Type Text: [Text] Action: [Text]

No clinically relevant sizes currently defined

Storage and Handling

Storage and Handling: [Text] Action: [Text]

No storage or handling currently defined



**Device Characteristics**

For Single-Use: ☐

Production Identifier(s) in UDI

Lot or Batch Number: [Text] [Add]

Serial Number: [Text] [Add]

Expiration Date: [Text] [Add]

Manufacturing Date: [Text] [Add]

Latex Information

Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 891.437): ☐

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Prescription Status

☐ Prescription Use (Rx) ☐ Over the Counter (OTC)

Clinically Relevant Size

Size Type Text: [Text] Action: [Text]

No clinically relevant sizes currently defined

Storage and Handling

Storage and Handling: [Text] Action: [Text]

No storage or handling currently defined





# 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

201201081532409427848\_Template\_미국 V0 최초 등록\_1 - Microsoft Excel

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P																
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' 포맷 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)																															
파트코드	파트 리비전	파트타입	인허가코드	생산코드	형태	리비전	상태	임플란트 미국																							
PLMVALR_01	0	ossIPart	PLMVALR_01	PLMVALR_01	N			(미국)허가 구분		(미국)품목 구분		(미국)인허가 완료일		(미국)허가(신고)번호																	
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	0																										
No	No	GS1	1	0	0																										
No	No	GS1	1	0	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				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																				
MRI Safety Status																															
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											

201201081532409427848\_Template\_미국 V0 최초 등록\_1 - Microsoft Excel

### FDA 510(K) information

reference	Reference for Product
PLMVALR_01	PLMVALR_01
PLMVALR_02	PLMVALR_02
PLMVALR_03	PLMVALR_03

임플란트 미국	(미국)허가 구분	(미국)품목 구분	(미국)인허가 완료일	(미국)허가(신고)번호	(미국)유효기간
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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)

파트코드	파트 리비전	파트타입	인허가코드	생산코드	형태	리비전	상태
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		

임플란트 미국	(미국)허가 구분	(미국)품목 구분	(미국)인허가 완료일	(미국)허가(신고)번호	(미국)유효기간
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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	0						
No	No	GS1	1	0	0						
No	No	GS1	1	0	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	No	No	No	No	No	No					

### UDI Device information

Product	Exempt from Premarket Submission	Supplement Number	DI Characteristics	For Single-Use	Lot or Batch Number	Serial Number	Expiration Date	Manufacturing Date	Donation Identification Number
		000	Yes	Yes	Yes	Yes	Yes	Yes	No
		000	Yes	Yes	Yes	Yes	Yes	Yes	No
		000	Yes	Yes	Yes	Yes	Yes	Yes	No

Device Information					
UDI 등록	UDI 제출	Issuing Agency	Device Count	DI Number	DUNS Number
No	No	GS1	1	0	0
No	No	GS1	1	0	0
No	No	GS1	1	0	0

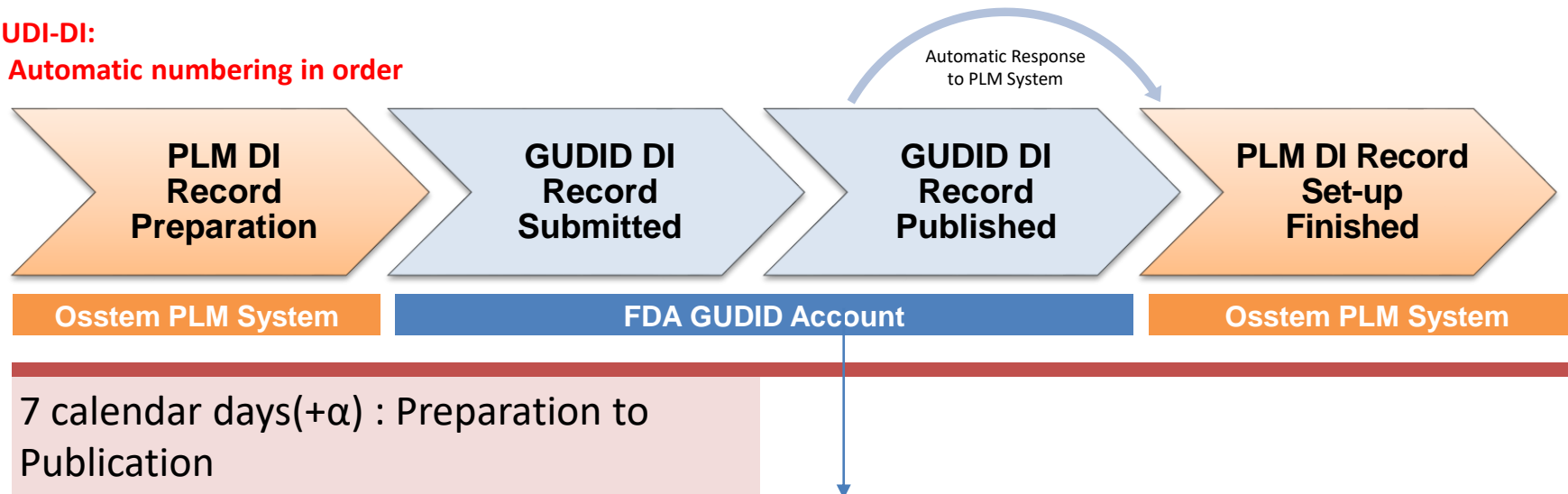
contain MRI Safety Information  
contain MRI Safety Information  
contain MRI Safety Information

# 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

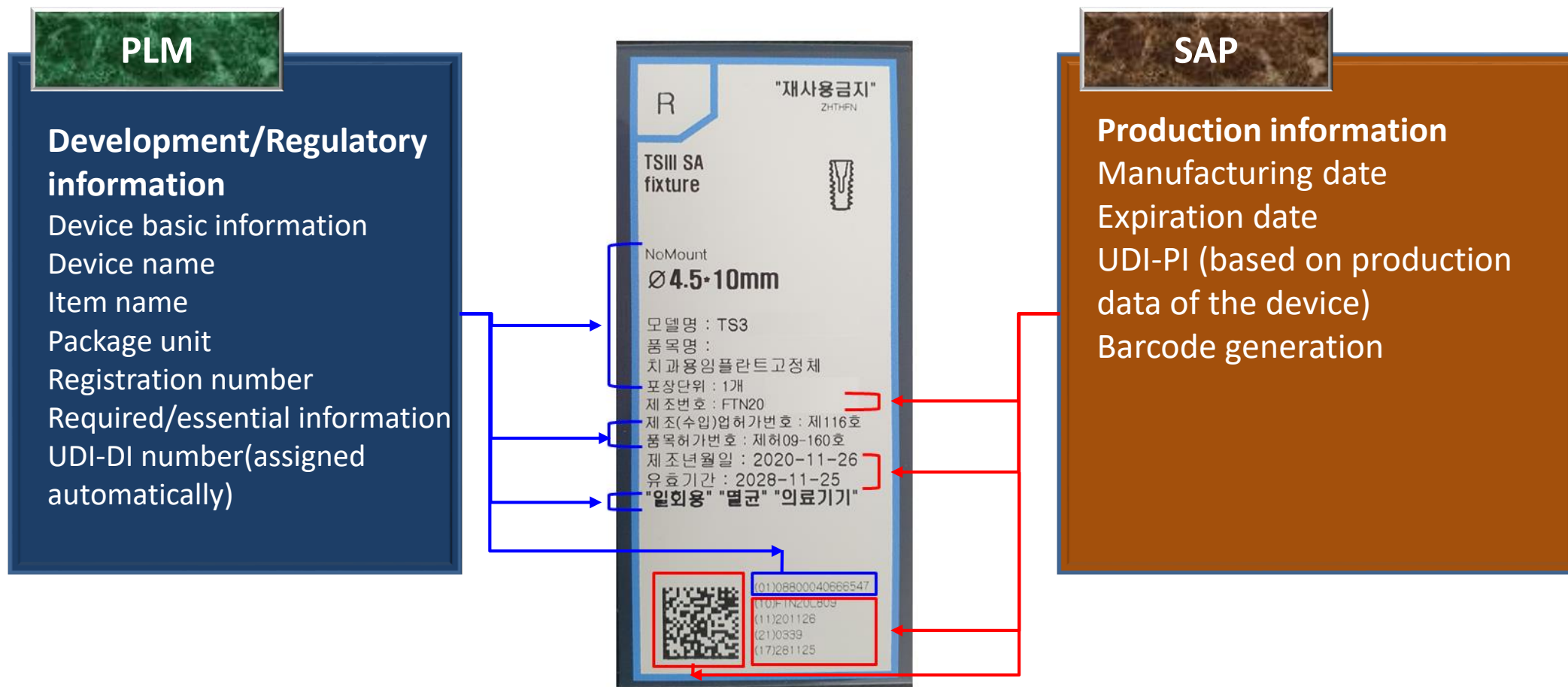


❖ Editing Limitation determined by the

❖ 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



## 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 <sup>th</sup> logistics barcode	Manual entry
Unit in 4 <sup>th</sup> 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!