



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.



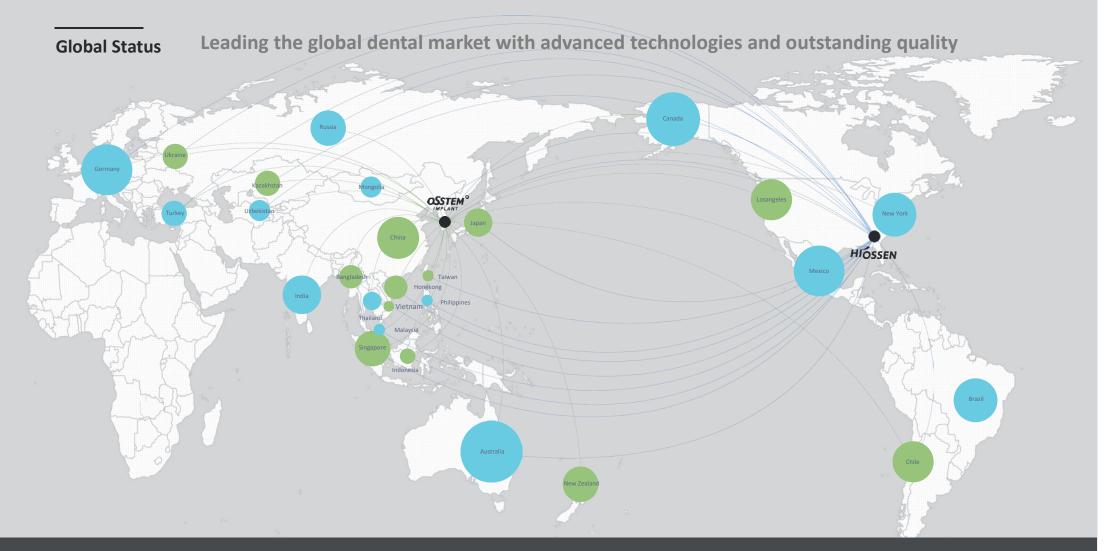
OSSTEM⁶ IMPLANT





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	 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)



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

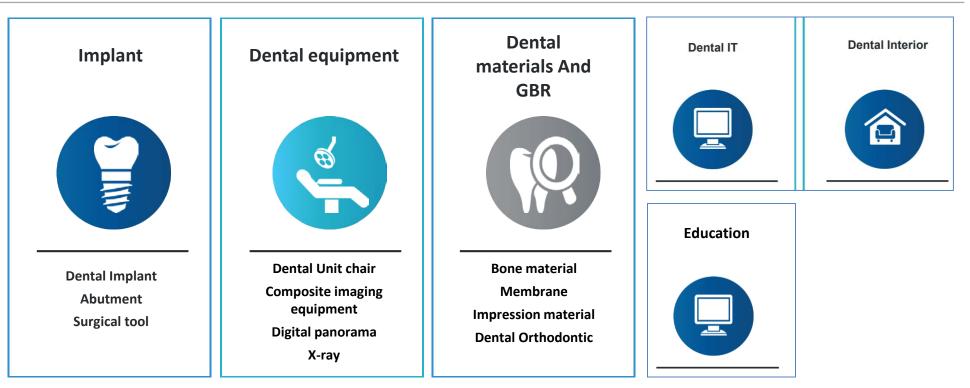
Exports products to more than 70 countries around the world

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

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





FDA GUDID submission module

Specification management for over 22 different countries

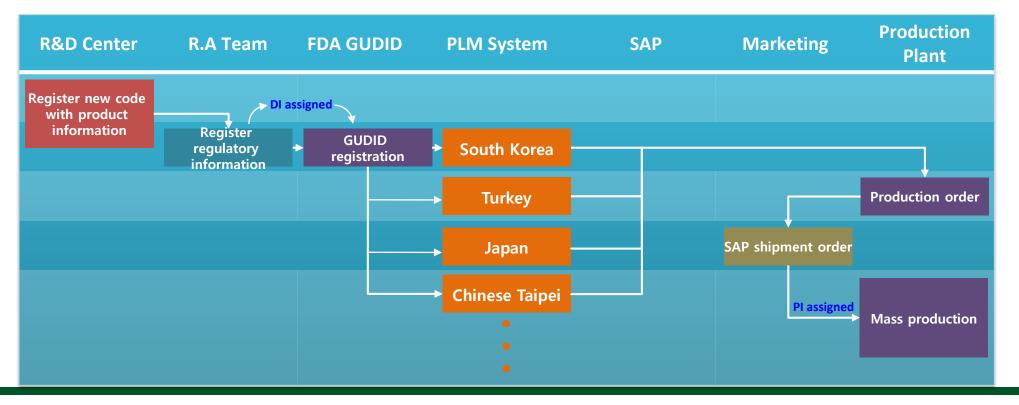
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- Possible to efficient industrial regulatory level management in global market
- Possible to minimize time to market and to efficient regulatory management with one COMPREHENSIVE system





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

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



DITTA 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

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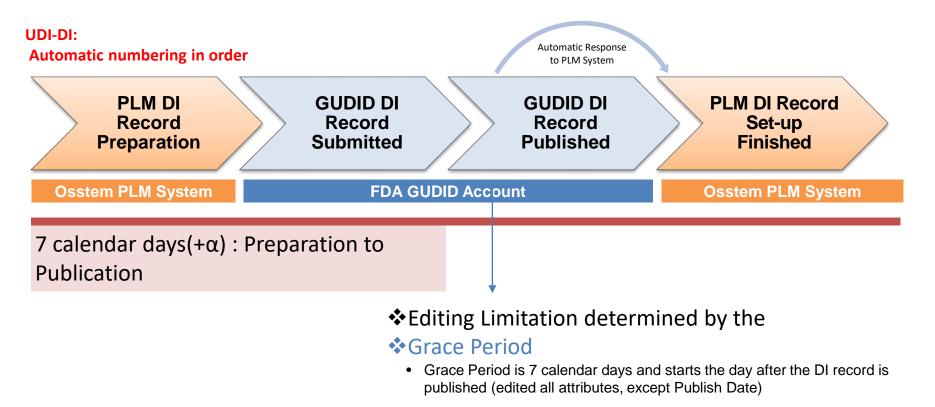
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FDA GUDID Registration Process



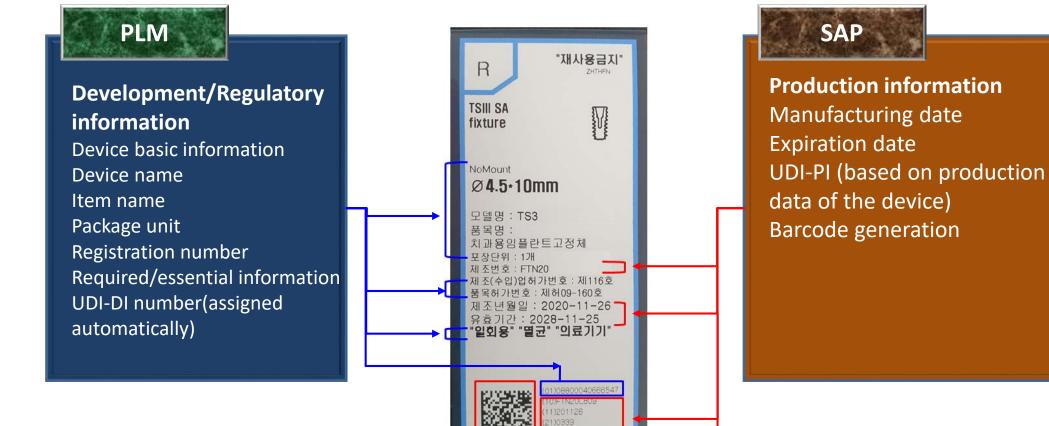
Set up the UDI Record via FDA GUDID Registration System which first introduced this UDI system to the world, and apply this same published UDI to all countries.





Example of PLM & SAP Labeling Application





12/19



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	Unified Information System	Explanation	Unified Information System	Explanation
Item serial number	Automatic entry of regulatory information	Phthalates	Entry selection (Y or N)	Sterilization method3_other	Manual entry
Model serial number	Automatic entry of regulatory information	MRI safety status	Entry selection (safe, unsafe etc.)	 Benefit claim	· · · · · · · · · · · · · · · · · · ·
Number	Automatic entry of regulatory information	Storage condition	Manual entry		Manual entry
Item number	Automatic entry of regulatory information	Distribution, handling	Manual entry	Benefit claim code1	Manual entry
Class	Automatic entry of regulatory information	condition		Benefit claim code2	Manual entry
Manufacture/Import	Automatic entry of regulatory information	Version	Manual entry	Benefit claim code3	Manual entry
Registration number	Automatic entry of regulatory information	Remark (Warn, caution or contraindication)	Manual entry	Benefit claim code4	Manual entry
Registration date	Automatic entry of regulatory information	Additional information	Manual entry	Benefit claim code5	, Manual entry
Model number	Automatic entry of regulatory information	Chief manager contact	Manual entry		
Issuing Agency	Entry selection (GS1, HIBBCC, ICCBBA)	Chief manager e-mail	Manual entry	Benefit claim code Reason for not entering	Manual entry
Device Identifier(UDI-DI)	0880000982809	Customer Service name	Manual entry		
Lot number	Entry selection (Y or N)	Customer Service contact	Manual entry	Secondary logistics barcode	Manual entry
Serial number	Entry selection (Y or N)	Require sterilization prior to		Unit in secondary package	Manual entry
Manufacturing date	Entry selection (Y or N)	use	Entry selection (Y or N)	Tertiary logistics barcode	Manual entry
Expiration date	Entry selection (Y or N)	Sterilization method1	Entry selection (Steam, gamma etc.)	Unit in tertiary package	Manual entry
Sterilization	Entry selection (Y or N)	Sterilization method1_other	Manual entry		
Package unit	Manual entry	Sterilization method2	Entry selection (Steam, gamma etc.)	4 th logistics barcode	Manual entry
Latex	Entry selection (Y or N)	Sterilization method2_other	Manual entry	Unit in 4 th package	Manual entry
		Sterilization method3	Entry selection (Steam, gamma etc.)		





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





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





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)





Thank you!