APACMed Workshop
Update on UDI Implementation & ASPAC Regional Trend

Victoria Qu

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AGENDA

- ❑IMDRF UDI Rule & Implementation Guidance
  - UDI System Framework
- ❑UDI Implementation in US
- ❑ASPAC Current Status
- ❑Suggestions

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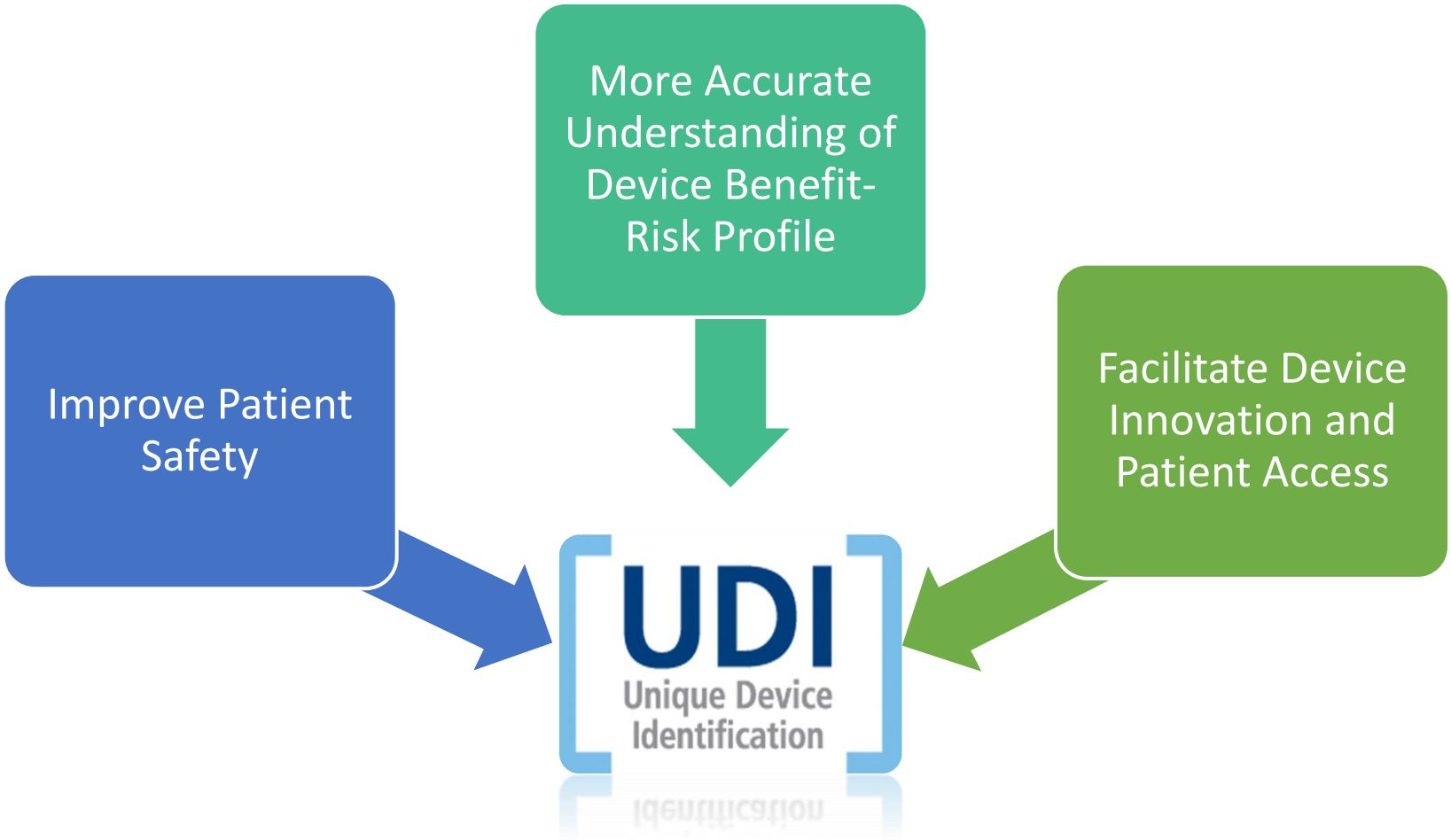
ASPAC Need UDI to…



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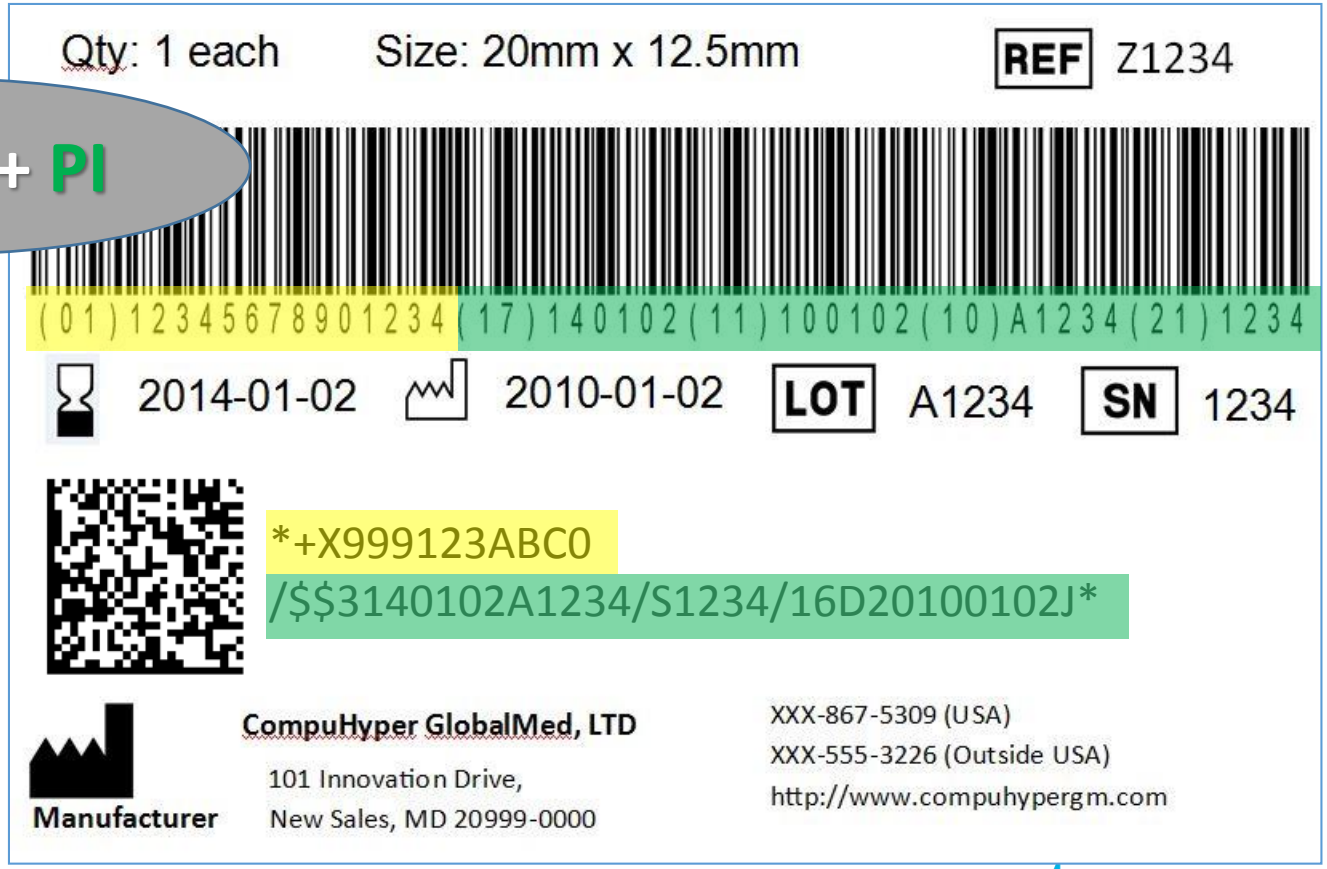
What is a UDI?

Required on the device label, packages or, in some cases, on the device itself

Code in plain text and machine readable format (AIDC)

UDI = DI + PI



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International Medical Device Regulators Forum (IMDRF) UDI Work Group

IMDRF International Medical Device Regulators Forum

2. Introduction

This guidance provides a framework for those regulatory authorities that intend to develop their own UDI Systems – such that, when implemented, it achieves a globally harmonized approach to UDI. It is expected that the regulatory authorities will follow the guidance when developing their own UDI requirements. The framework can be used at a local, national, or global level. In order to reach the goal of a globally harmonized UDI System, it is critical that these systems are implemented without regional or national differences.....

UDI WG Established under Global Harmonization Task Force (GHTF) October, 2008.

IMDRF Guidance
UDI for Medical Devices
Final Version,
December 9, 2013

http://www.imdrf.org/documents/documents.asp

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IMDRF UDI Application Guide – Proposed Draft


IMDRF/UDI WG_____

IMDRF International Medical Device Regulators Forum

PROPOSED WORKING DRAFT

International Medical Device Regulators Forum

Title: Unique Device Identification (UDI) Application Guide

Authoring Group: IMDRF UDI WG

Date:

RATIONAL:

Global UDI system is intended to provide a single, globally-accepted system for positive identification of medical devices.

The IMDRF UDI Guidance document **does not contain the level of detail needed for a globally harmonized approach to the implementation** of a UDI system.

Introduction of the IMDRF UDI Guidance IMDRF "This guidance is intended to provide a high-level conceptual view of how a global UDI System should work. **It is recognized that further additional guidance may be needed once these core concepts are accepted**." (IMDRF/WG/N7Final:2013)

WORK ITEM PROPOSAL

To develop an Application Guide for UDI that will **facilitate implementation of a globally harmonized approach to UDI**

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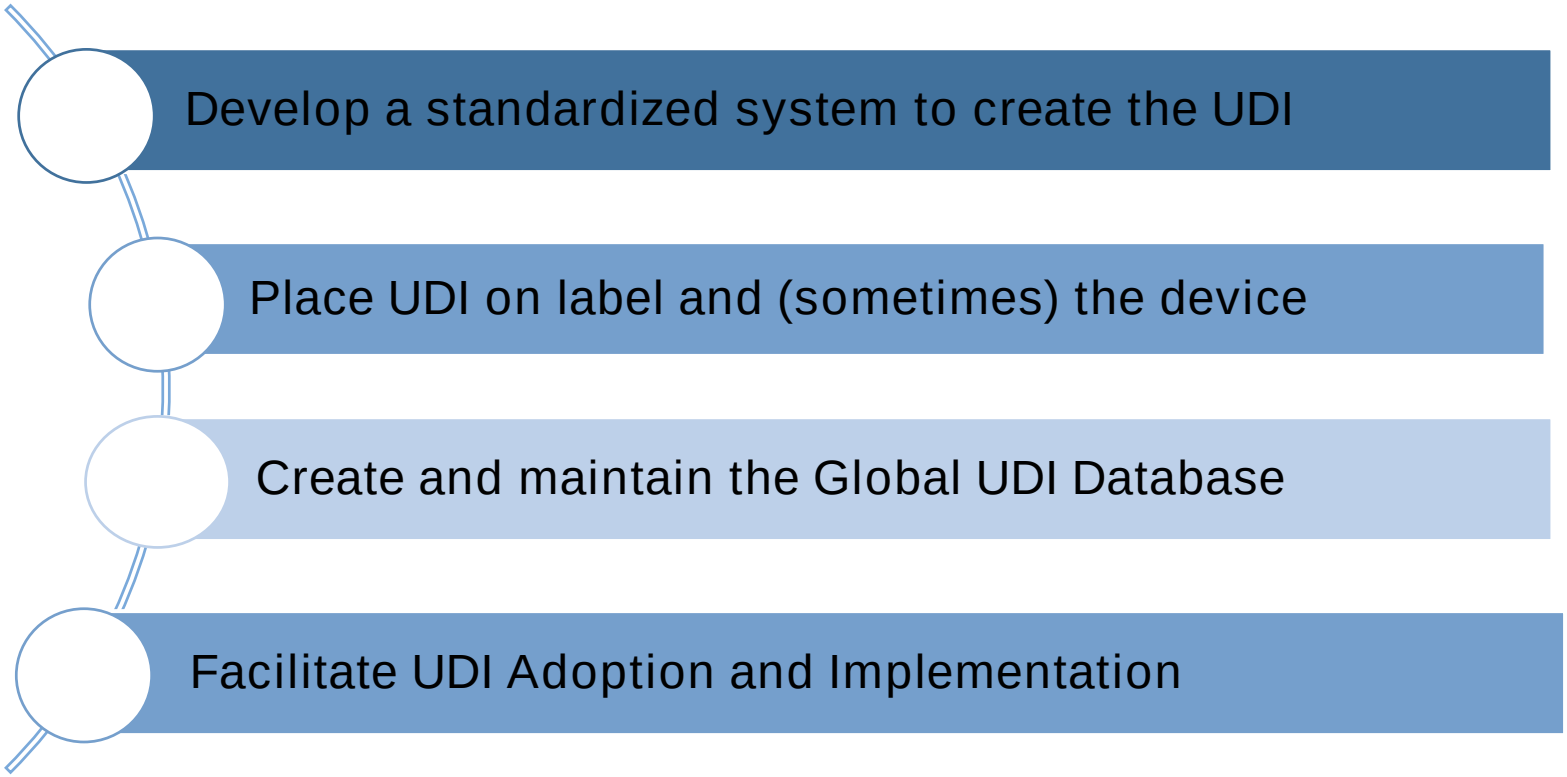
US Implementation

Four Critical Steps For A Successful UDI Implementation



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The Fundamental Concepts Of A Globally Harmonized UDI System Include:

- ✓ The UDI and UDI carrier are based on **global standards**
- ✓ A UDI applied to a medical device anywhere in the world should be able to be **used globally and to meet the UDI requirements** of its regulatory authority
- ✓ National or local identification numbers should **NOT be a substitute for UDI**
- ✓ Regulatory authorities **should not specify the procedure for modifying** these UDI standards
- ✓ The UDI database (UDID) **core elements should not be modified**
- ✓ The UDID should use the health level seven(HL7) **international structured product label (SPL) and web based interface for data submission**
- ✓ **Every medical device needs to be identified by a UDI**, unless it is exempted

GUDID Search and Retrieval

GUDID Global Unique Device Identification Database

Repository of key device identification information

Contains ONLY the DI; PIs are not submitted to nor stored in the GUDID

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

- **May 4, 2015: Launch of Beta AccessGUDID** accessgudid.nlm.nih.gov
- **Partnered with the National Library of Medicine (NLM) to provide:**
  - Public Search
  - Database Download
  - Web Services
- **Releasable attributes of Published DI records are available**

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US Compliance Dates for UDI Requirements

Device	Label and GUDID Compliance Date
Class III (including Class III I/LS/LS[1])	24-Sep-14
Devices licensed under the PHS Act	
Implantable, Life-Supporting and Life-Sustaining (Class II, Class I & Unclassified)	24-Sep-15
Class II (other than I/LS/LS[1])	24-Sep-16
Class I or Unclassified (other than I/LS/LS[1])	24-Sep-20
Direct Mark (21 CFR 801.45) Requirements Class I or Unclassified	24-Sep-22

[1] Implantable/Life-Supporting/Life-Sustaining

ASPAC Initiatives

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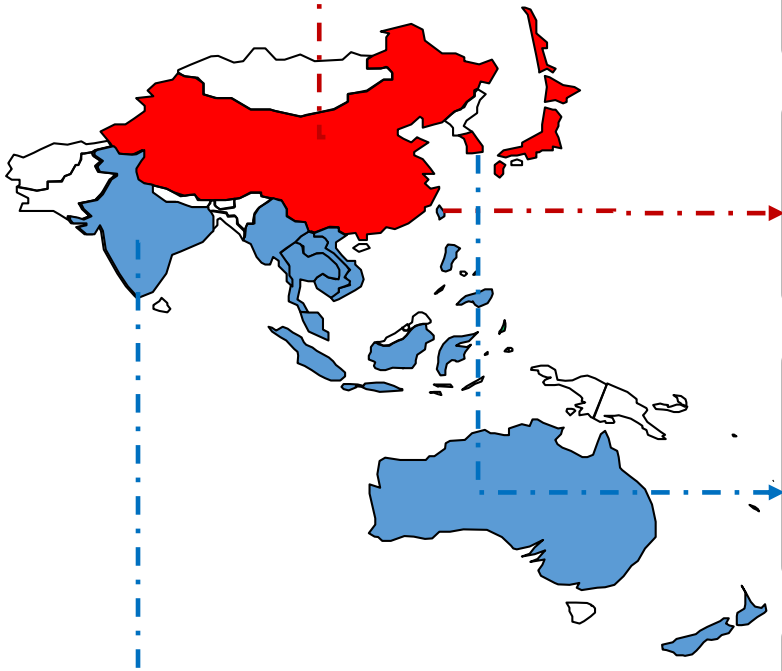
UDI Deployment and Pilot in ASPAC



- UDI Rule under discussion
- Healthcare Institution and supply chain driven track and trace
- Monitor the UDI implementation

Chinese Taipei

Voluntary UDI guidance issued and implemented in Oct. 2015.

MFDS revised its Medical Device Act on Dec 2, 2016

- MFDS set up local 'device integration data system center' to handle the UDI database
- More implementation details to be released soon.
- Compliance time line

Medical Device Rule, UDI composed by DI and PI must be applicable to all licensed device from Jan. 1st, 2022.

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UDI Investigation & Development in China

US Implementation	EU MDR & IVDR	IMDRF	China Local MKT
US FDA Visit in 2016	CSDR UDI Research Group in 2017	UDI Rule Discussion and Feedback	Meeting with various stakeholders Monitor development of Purchase Coding Traceability Standard development

RESEARCH & INVESTIGATION

- State Council Office <Opinion On Promote The Establishment Of Traceability System For Important Products>
- 13FYP On Drug Safety Guidance (2016-2020)
- CFDA Opinion On Promote Food And Drug Manufacturer And Distributors To Improve The Traceability System (2016 No. 122)

- **Basic Principle**
  - China local mkt situation + global best practice
  - Streamline R&R for govn't and industry
  - Phased-in approach
- **Development Goal and Main Content**
  - UDI Coding
  - Database
  - Implementation

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UDI Development in India

- New Medical Device Rules, 2017 have been published by Government of India via Gazette Notification GSR 78(E) on **January 31, 2017**.

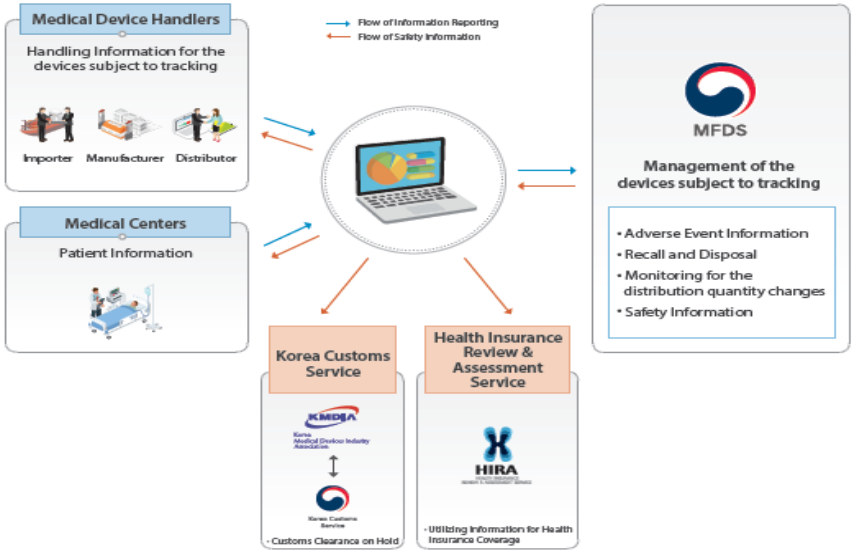
- These rules shall, unless specified otherwise, come into force with effect from **January 1, 2018**.

46. Unique device identification of the medical device.— *With effect from 1st day of January, 2022, a medical device, approved for manufacture for sale or distribution or import, shall bear unique device identification which shall contain device identifier and production identifier.*

Explanation.— For the purposes of this rule,-
(i) "device identifier" means a global trade item number;.
(ii) "production identifier" means a serial number, lot or batch number, software as a medical device version, manufacturing and or expiration date.

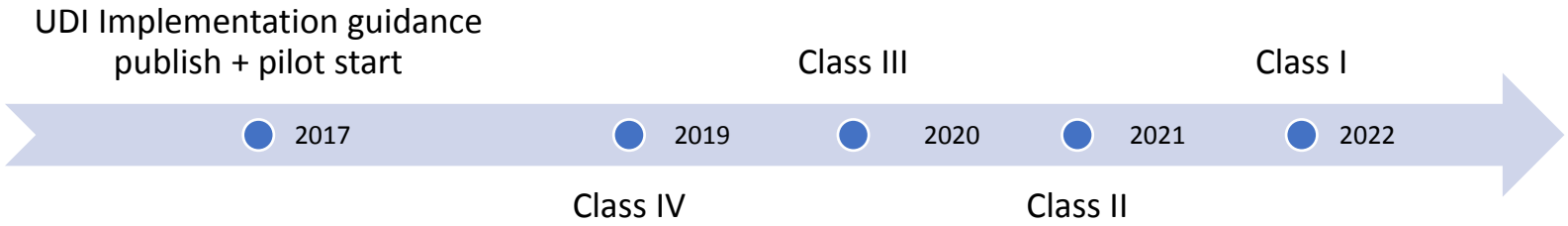
UDI Investigation & Development in S. Korea

MFDS has designated 52 implantable and life-supporting medical devices, which are subject to tracking for patient safety.



MFDS collects information about devices and patients from manufacturers and importers to regulate the safe use of those devices and prevent medical incidents.

- Harmonization with global standard & regulation (Under discussion)
  - ✓ UDI format: GS1 basis
  - ✓ UDI database: MDITAC
  - ✓ Pilot to start in Nov. 2017
- Legislated reporting of medical device supply history with UDI
  - ✓ Reporter: MD manufacturers, importers, distributors, and lessors
  - ✓ Reporting items(Under discussion) : UDI, supply information incl. unit price



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Industry Suggestions – AdvaMed White Paper

1. Utilization of a Phased-In and Risk-Based Approach
2. Reliance on Standards and Globally Accredited Issuing Agencies
3. Access to Information; Submission Methods
4. Providing Assistance to Industry: Help Desk, Training and Guidance
5. Exceptions, Exemptions, Alternatives and Extensions

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THANK YOU.....

DO YOU HAVE ANY QUESTIONS ?

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