

# Regulatory Convergence and Reliance

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# Regulatory Reality

- National Regulatory Authorities (NRAs) are a critical part of access to safe, effective and innovative medical products.
- The degree to which NRAs perform their functions effectively and transparently directly impacts access and innovation, and ultimately public health.
- To fulfill our mandate as ARN we must consider regulatory models that consider available resources, increasingly complex technologies, the globalization of supply chains, and the expectations of our population.

# Regulatory Convergence for Regulatory Collaboration



- Regulatory convergence is expected to reduce duplication of work by creating a common language for the regulatory decision-making process that facilitates cooperation, worksharing, and eventually reliance.
- For regulatory convergence to be successful, changes in the regulatory approach are also required to allow for collaboration and reliance.

# Regulatory Cooperation



Feedback

Information Exchange

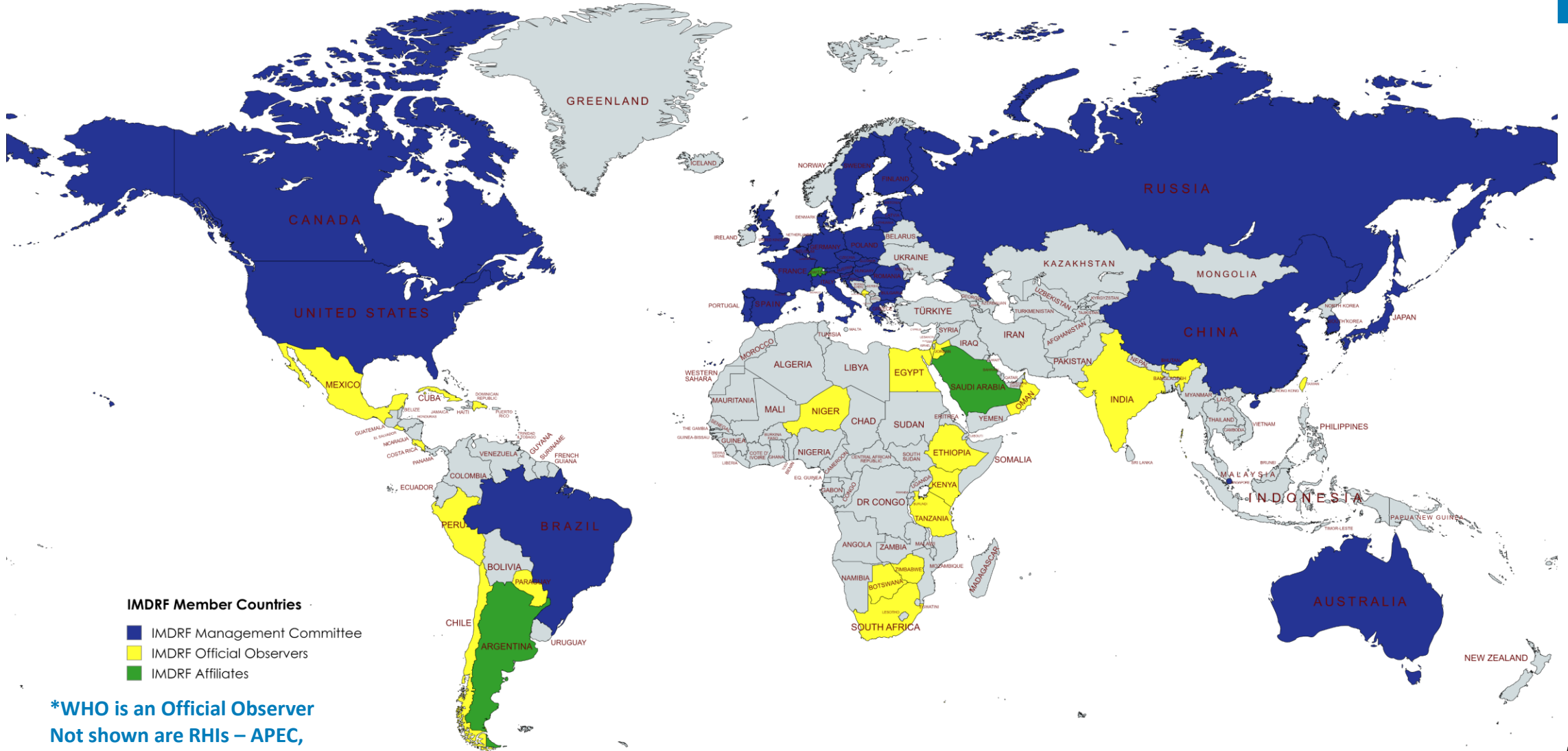
Convergence

Equivalence Assessment

Worksharing, reliance

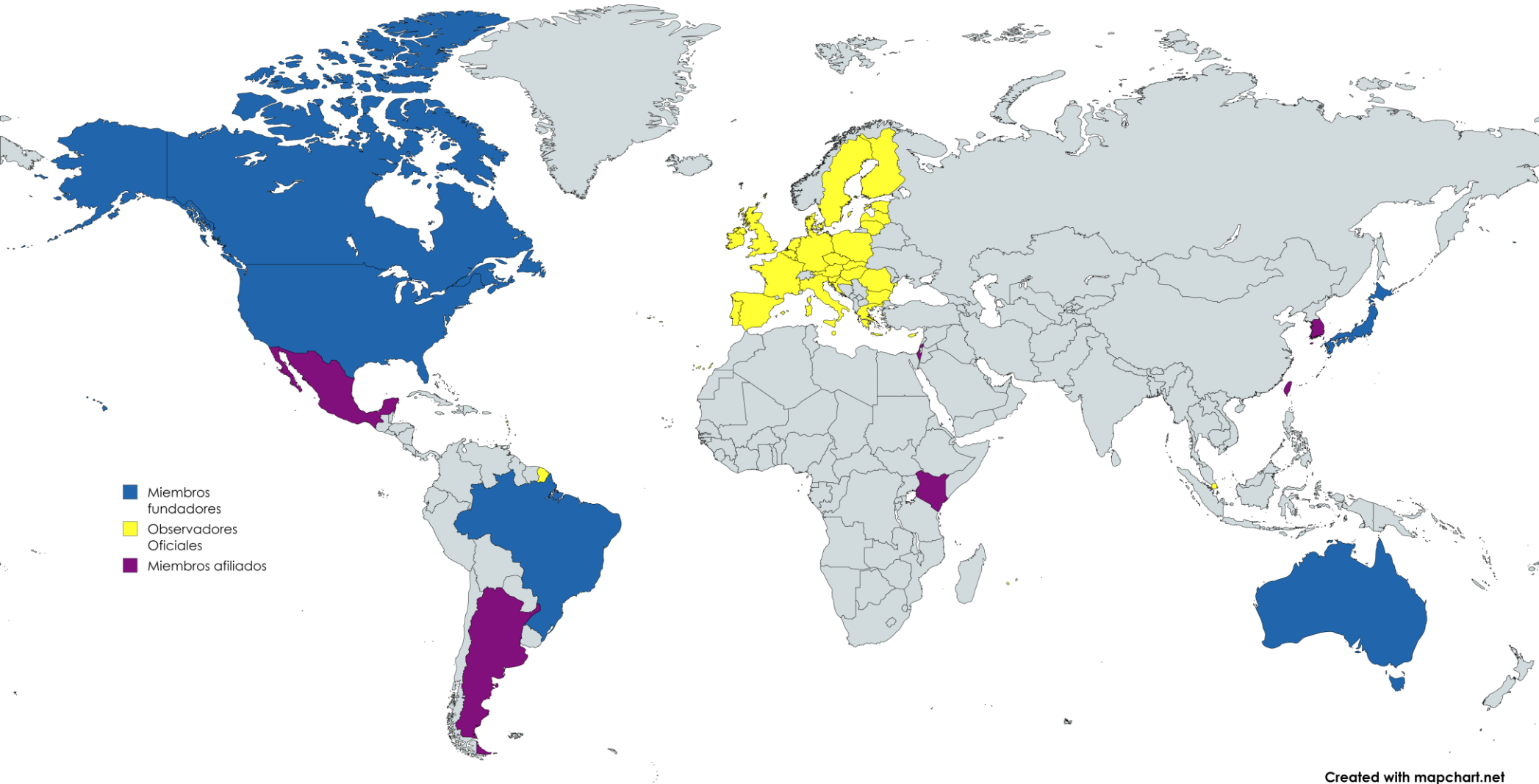
Unilateral/mutual recognition

# IMDRF Members



**\*WHO is an Official Observer**  
**Not shown are RHIs – APEC,**  
**AMDF, GHWP, PAHO**

# MDSAP Members



# Participation of the Americas in global Regulatory Convergence initiatives



## IMDRF



- Members: Brazil, Canada, United States
- Observer: Argentina
- Affiliate Members: Chile, Costa Rica, Cuba, Dominican Republic, El Salvador, Mexico, Peru, Paraguay

## MDSAP



- Members: Brazil, Canada, United States
- Affiliate Members: Argentina and Mexico

# Challenges



International vs. domestic standards

International cooperation vs. Other Priorities

Consistent Implementation

Active participation in global initiatives

## Equivalence Assessment

- World health Organization “Global Benchmarking Tool” (GBT) /WLA
- Regulatory Landscape in the Americas

## Reliance

- MDSAP
- Databases

# Product Classification Database

## Product Classification

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This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA Premarket Review organizations, and other regulatory information.

[learn more...](#)

### Search Database



Help



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Device

Product Code

Review Panel

Regulation Number

Submission Type

Third Party Eligible

Implanted Device

Life-Sustain/Support Device

Device Class

Summary Malfunction Reporting

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search

[www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm)

# Method 1:

# Product Classification Database

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This database includes:

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### Search Database



Help



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Device

non-invasive blood pressure

Product Code

Review Panel

Regulation Number

Submission Type

Third Party Eligible

Implanted Device

Life-Sustain/Support Device

Device Class

Summary Malfunction Reporting

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search

New Search		Back To Search Results
Device	System, Measurement, Blood-Pressure, Non-Invasive	
Regulation Description	Noninvasive blood pressure measurement system.	
Regulation Medical Specialty	Cardiovascular	
Review Panel	Cardiovascular	
Product Code	DXN	
Premarket Review	<a href="#">Office of Device Evaluation (ODE)</a> Division of Cardiovascular Devices (DCD) Cardiac Diagnostics Devices Branch (CDDDB)	
Submission Type	510(k)	
Regulation Number	870.1130	
Device Class	2	
Total Product Life Cycle (TPLC)	<a href="#">TPLC Product Code Report</a>	
GMP Exempt?	No	
Recognized Consensus Standards	<ul style="list-style-type: none"> <li>3-122 ISO 81060-2 Second edition 2013-05-01  <a href="#">Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type</a></li> <li>3-123 IEC 80601-2-30 Edition 1.1 2013-07  <a href="#">Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers</a></li> <li>13-57 IEEE ISO 11073-10407 First edition 2010-05-01  <a href="#">Health informatics - Personal health device communication - Part 10407: Device Specialization - Blood pressure monitor</a></li> </ul>	
Implanted Device?	No	
Life-Sustain/Support Device?	No	
Third Party Review	<ul style="list-style-type: none"> <li>Eligible for <a href="#">Accredited Persons Program</a></li> </ul>	
Accredited Persons	<ul style="list-style-type: none"> <li><a href="#">Center For Measurement Standards Of Industrial</a></li> <li><a href="#">Regulatory Technology Services, Llc</a></li> <li><a href="#">Third Party Review Group, Llc</a></li> <li><a href="#">Tuv Sud America Inc.</a></li> </ul>	

Product Code

Regulation Number & Device Class

## Method 2: Search for Device by clearance/approval



- **510(k) Clearance**

[www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm)

- **PMA Approval**

[www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm)

- **De Novo Database**

[www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm)

# Method 2: Search by 510(k) Clearance

## 510(k) Premarket Notification

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A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR §807.92(a)(3)) that is not subject to premarket approval.

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### Search Database



Help



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510K Number	<input type="text"/>	Type	<input type="text"/>	Product Code	<input type="text"/>
Center	<input type="text"/>	Combination Products	<input type="checkbox"/>		
Applicant Name	<input type="text"/>	Cleared/Approved In Vitro Products	<input type="checkbox"/>		
Device Name	<input type="text"/>	Redacted FOIA 510(k)	<input type="checkbox"/>		
Panel	<input type="text"/>	Third Party Reviewed	<input type="checkbox"/>		
Decision	<input type="text"/>				
Decision Date	<input type="text"/>	to	<input type="text"/>	Clinical Trials	<input type="checkbox"/>
Sort by	Decision Date (descending) <input type="text"/>				
<a href="#">Quick Search</a>			<a href="#">Clear Form</a> <input type="button" value="Search"/>		

# Method 2: Search by 510(k) Clearance

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
# Method 2: Search by 510(k) Clearance

## 510(K) Premarket Notification

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1 to 4 of 4 Results  
 for *Non-Invasive Blood Pressure Device*

10  results per page

<a href="#">New Search</a>		 <a href="#">Export To Excel</a>    <a href="#">Help</a>	
Device Name  	Applicant  	510(K) Number  	Decision Date  
<a href="#">Welch Allyn Non Invasive Blood Pressure (NIBP) Device</a>	WELCH ALLYN, INC.	<a href="#">K093907</a>	04/14/2010
<a href="#">TI-300 T-Line Non-Invasive Blood Pressure Monitoring System</a>	United States GTM Medical Devices, Inc.	<a href="#">K123446</a>	12/07/2012
<a href="#">Non-Invasive Hemodynamic Blood Pressure Monitor</a>	Vita-Course Technologies Co., Ltd.	<a href="#">K190893</a>	08/07/2019
<a href="#">Monitor, Non-Invasive Blood Pressure</a>	AUTOMATED SCREENING DEVICES	<a href="#">K782000</a>	12/05/1978

# Method 3:

## Search Device Listing Database

### Establishment Registration & Device Listing

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This database includes:

- medical device manufacturers registered with FDA and
- medical devices listed with FDA

Note: Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the establishment or its products by FDA.

[Learn More...](#)

#### Search Database

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Establishment or Trade Name	<input type="text"/>	Registration or FEI Number	<input type="text"/>
Owner/Operator Name	<input type="text"/>	Owner/Operator Number	<input type="text"/>
Proprietary Name	<input type="text"/>	Classification Device Name	<input type="text"/>
Product Code	<input type="text"/>	Establishment Type	<input type="text" value="v"/>
Establishment State (U.S.)	<input type="text" value="v"/>	Establishment Country	<input type="text" value="v"/>

[Quick Search](#)

[Clear Form](#)

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>

# Method 3:

## Search Device Listing Database

### Establishment Registration & Device Listing

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1 to 10 of 500 Results found  
for Non-Invasive Blood Pressure Device

[1](#)
[2](#)
[3](#)
[4](#)
[5](#)
[6](#)
[7](#)
[8](#)
[9](#)
[10](#)
[>](#)

Results per Page  [New Search](#)

Establishment Name	Product
<a href="#">7E LLC</a> Miami, FL	<a href="#">[show all products for 7E LLC Miami, FL]</a>
<a href="#">A&amp;D Company Limited - Tech Center</a> Kitamoto-Shi Saitama JP	<a href="#">Ambulatory Blood Pressure Monitor; TM-2430; TM-2430-DP3</a> <a href="#">[show all products for A&amp;D Company Limited ... Kitamoto-shi Saitama JP]</a>
<a href="#">A&amp;D ELECTRONICS (SHENZHEN) CO., LTD.</a> Shenzhen Guangdong CN	<a href="#">DIGITAL BLOOD PRESSURE MONITOR; UB-512; UB-521; UB-542</a> <a href="#">[show all products for A&amp;D ELECTRONICS (SHE ... Shenzhen Guangdong CN]</a>
<a href="#">A&amp;D ELECTRONICS (SHENZHEN) CO., LTD.</a> Shenzhen Guangdong CN	<a href="#">blood pressure monitor; UA-767PC; UA-767PCJ</a> <a href="#">[show all products for A&amp;D ELECTRONICS (SHE ... Shenzhen Guangdong CN]</a>
<a href="#">A&amp;D ENGINEERING, INC.</a> SAN JOSE, CA	<a href="#">blood pressure monitor; UA-767PC; UA-767PCJ</a> <a href="#">[show all products for A&amp;D ENGINEERING, INC ... SAN JOSE, CA]</a>
<a href="#">A.B. DENTAL DEVICES LTD</a> Ashdod HaDarom IL	<a href="#">[show all products for A.B. DENTAL DEVICES ... Ashdod HaDarom IL]</a>
<a href="#">AAT Medical LTD</a> Malta San Gwann MT	<a href="#">[show all products for AAT Medical LTD Malta San Gwann MT]</a>
<a href="#">AB ULAX</a> MOTALA Östergötlands län [SE-05] SE	<a href="#">[show all products for AB ULAX MOTALA Östergötlands län [SE-05] SE]</a>
<a href="#">ABBOTT DIABETES CARE INC.</a> ALAMEDA, CA	<a href="#">and Ketone Monitoring System; Precision PCx Plus Blood Glucose Test Strips; Precision Xceed Pro Blood Glucose; Precision Xceed Pro Blood Glucose Test Strips and Precision Xceed Pro Blood B-Ketone Test Strips</a> <a href="#">[show all products for ABBOTT DIABETES CARE ... ALAMEDA, CA]</a>
<a href="#">ABBOTT DIABETES CARE INC.</a> ALAMEDA, CA	<a href="#">and Ketone Monitoring System; Precision PCx Plus Blood Glucose Test Strips; Precision Xceed Pro Blood Glucose; Precision Xceed Pro Blood Glucose Test Strips and Precision Xceed Pro Blood B-Ketone Test Strips</a> <a href="#">[show all products for ABBOTT DIABETES CARE ... ALAMEDA, CA]</a>

# Method 3:



<a href="#">New Search</a>	<a href="#">Back To Search Results</a>
<b>Device Classification Name</b>	<a href="#">Accelerator, Linear, Medical</a>
<b>510(k) Number</b>	K232489
<b>Device Name</b>	VenusX
<b>Applicant</b>	LinaTech LLC 1294 Kifer Road #705 Sunnyvale, CA 94086
<b>Applicant Contact</b>	Jonathan Yao
<b>Correspondent</b>	LinaTech LLC 1294 Kifer Road #705 Sunnyvale, CA 94086
<b>Correspondent Contact</b>	Jonathan Yao
<b>Regulation Number</b>	<a href="#">892.5050</a>
<b>Classification Product Code</b>	<a href="#">IYE</a>
<b>Date Received</b>	08/17/2023
<b>Decision Date</b>	04/12/2024
<b>Decision</b>	Substantially Equivalent (SESE)
<b>Regulation Medical Specialty</b>	Radiology
<b>510k Review Panel</b>	Radiology
<b>Summary</b>	<a href="#">Summary</a>
<b>Type</b>	Traditional
<b>Reviewed by Third Party</b>	No
<b>Combination Product</b>	No

# Benefits – Outcome



Improve knowledge about NRA regulatory processes to facilitate reliance mechanisms and optimize resource use



Strengthening the regulatory capacity of authorities in the region.



Promote participation in global initiatives and use of international standards which improves access to innovative medical products.



Rapid response to emergency situations.



More agile regulatory processes in the region through alignment while maintaining a high level of regulatory oversight.

***Thank you!***