U.S. FOOD & DRUG ADMINISTRATION

Regulatory Convergence and Reliance

Patricia Pineda
Regulatory International Analyst
Latin America Office
Office of Global Operations

November 13, 2024

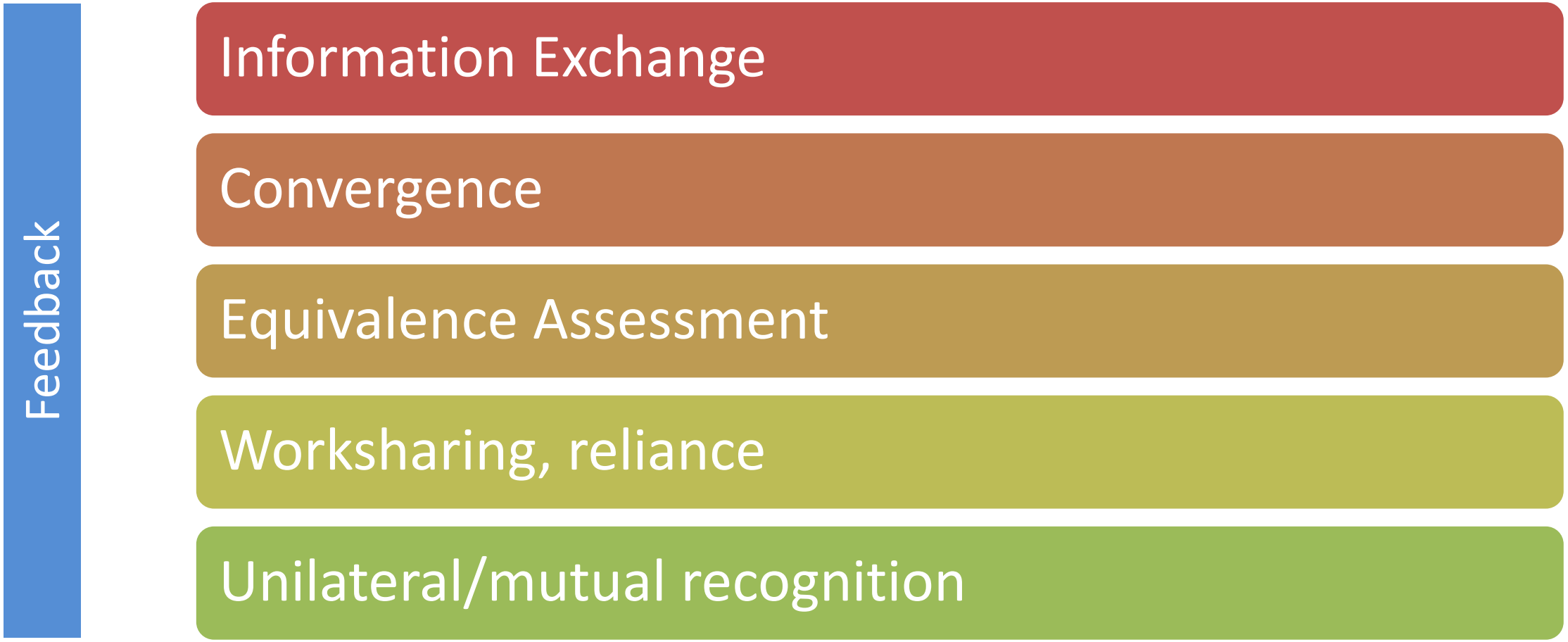
Regulatory Reality

- 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.

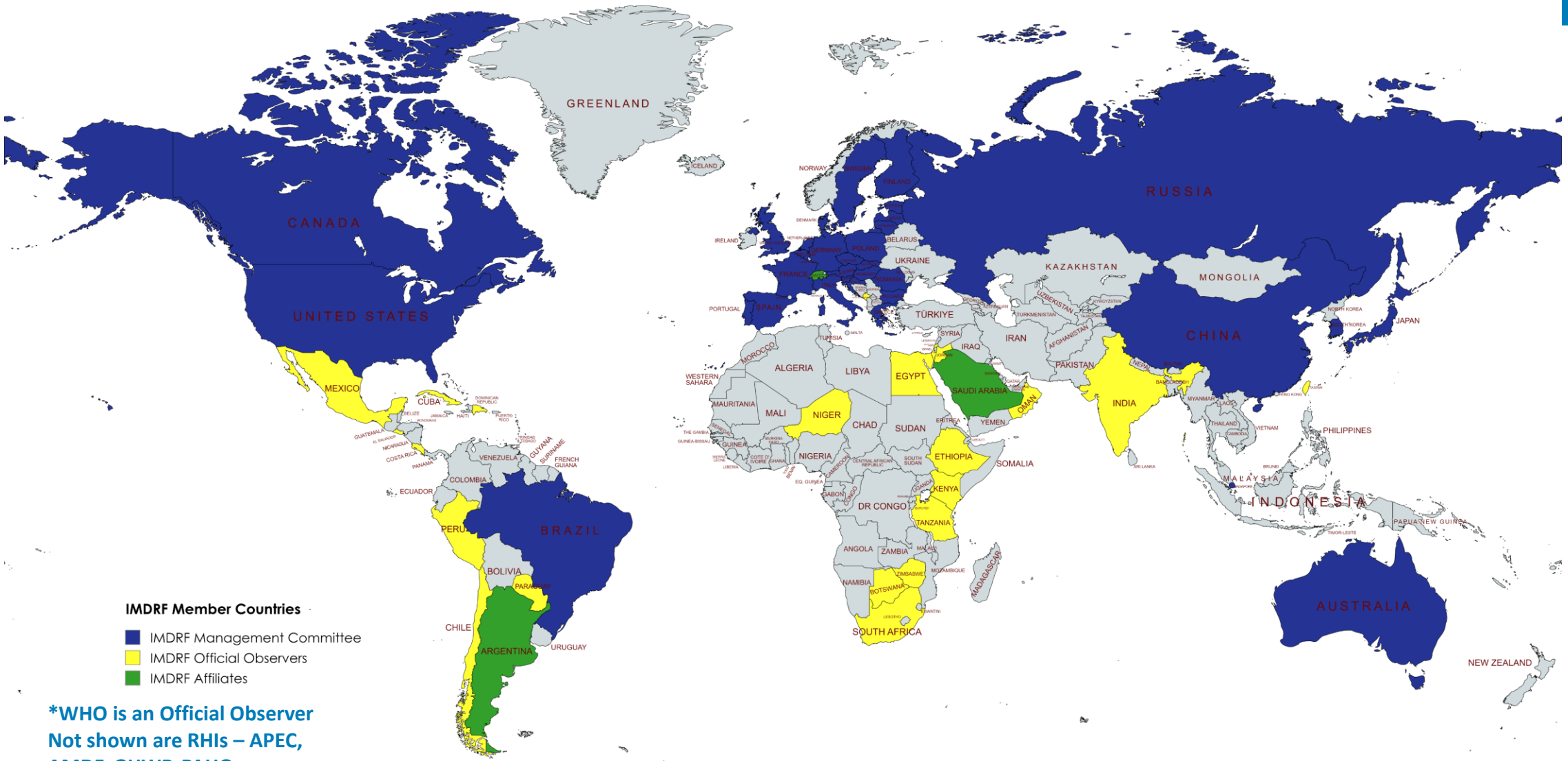
Regulatory Convergence for Regulatory Collaboration

- 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



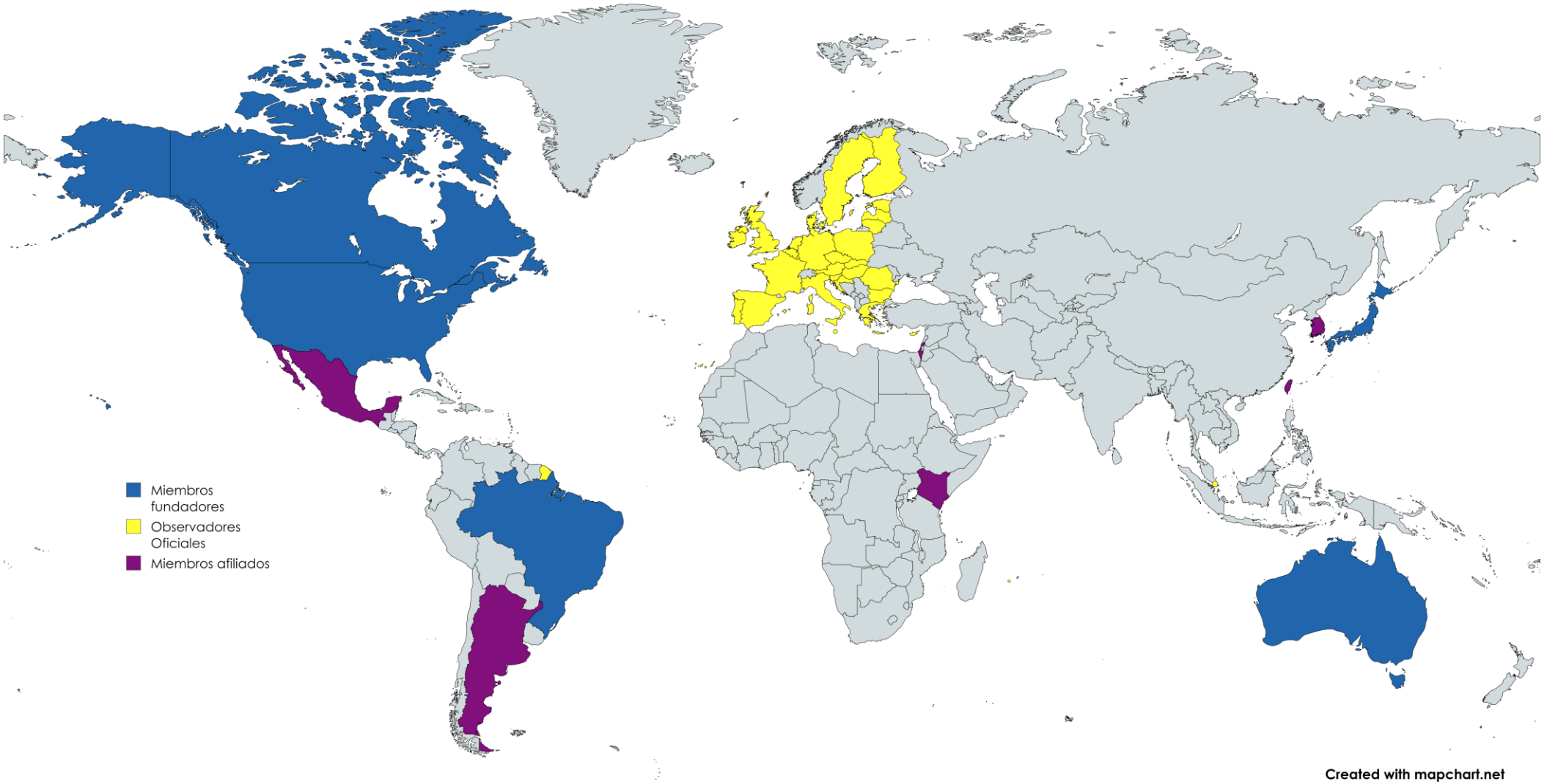
IMDRF Members



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

Created with mapchart.net

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

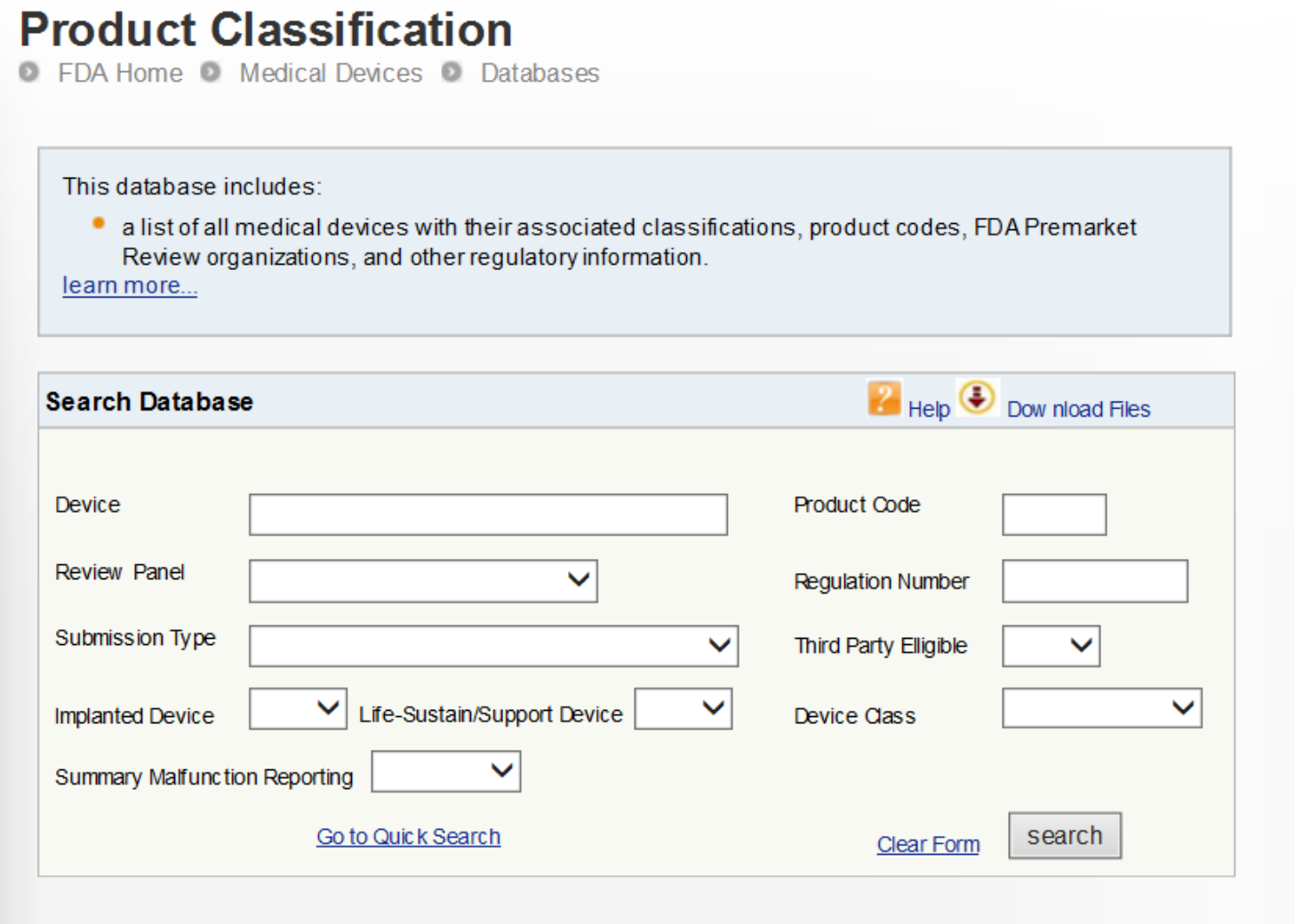
Equivalence Assessment

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

Reliance

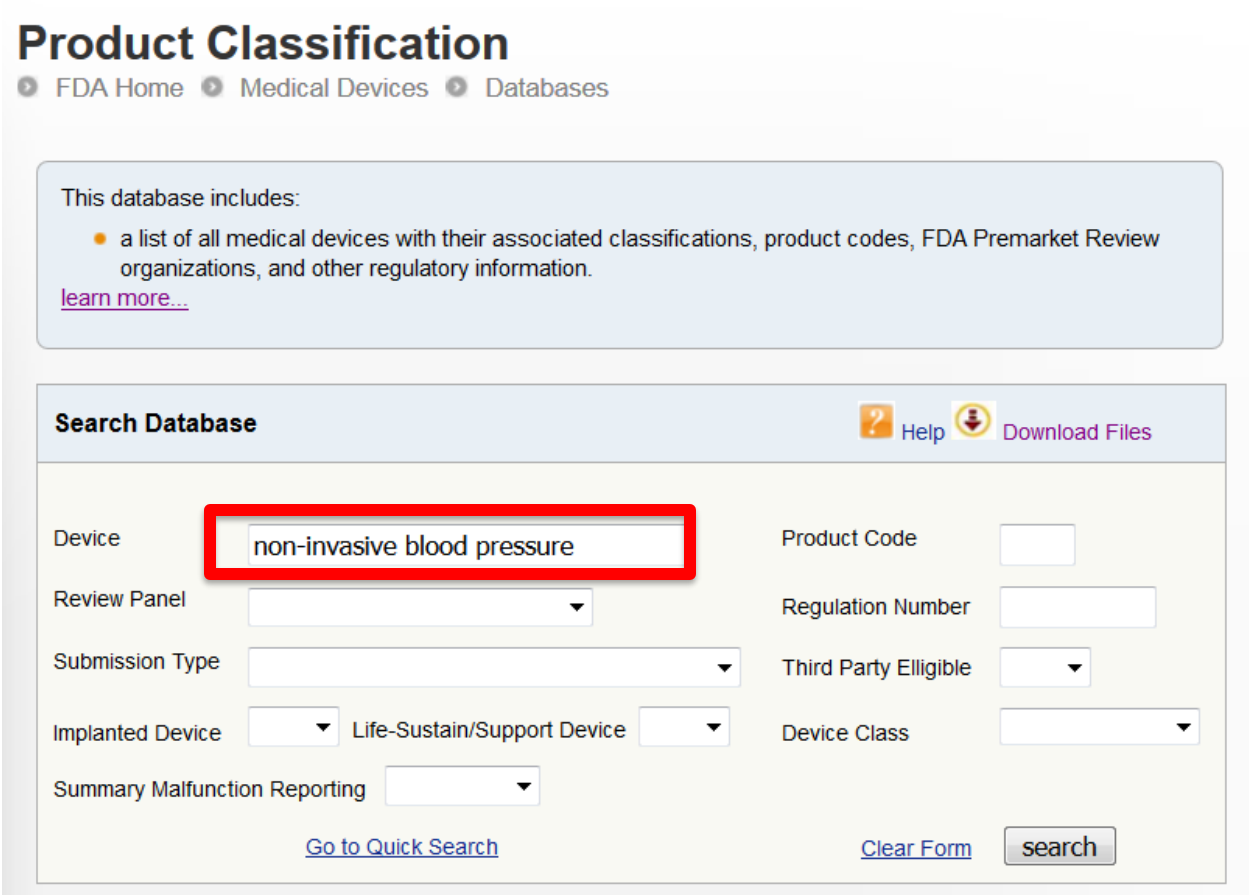
- MDSAP
- Databases

Product Classification Database



www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

Method 1:
Product Classification Database



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	Office of Device Evaluation (ODE) Division of Cardiovascular Devices (DCD) Cardiac Diagnostics Devices Branch (CDDB)
Submission Type	510(k)
Regulation Number	870.1130
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Recognized Consensus Standards

- 3-122 ISO 81060-2 Second edition 2013-05-01
  Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
- 3-123 IEC 80601-2-30 Edition 1.1 2013-07
  Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- 13-57 IEEE ISO 11073-10407 First edition 2010-05-01
  Health informatics - Personal health device communication - Part 10407: Device Specialization - Blood pressure monitor

Implanted Device?	No
Life-Sustain/Support Device?	No

Third Party Review

- Eligible for *Accredited Persons Program*

Accredited Persons

- Center For Measurement Standards Of Industrial
- Regulatory Technology Services, Llc
- Third Party Review Group, Llc
- Tuv Sud America Inc.

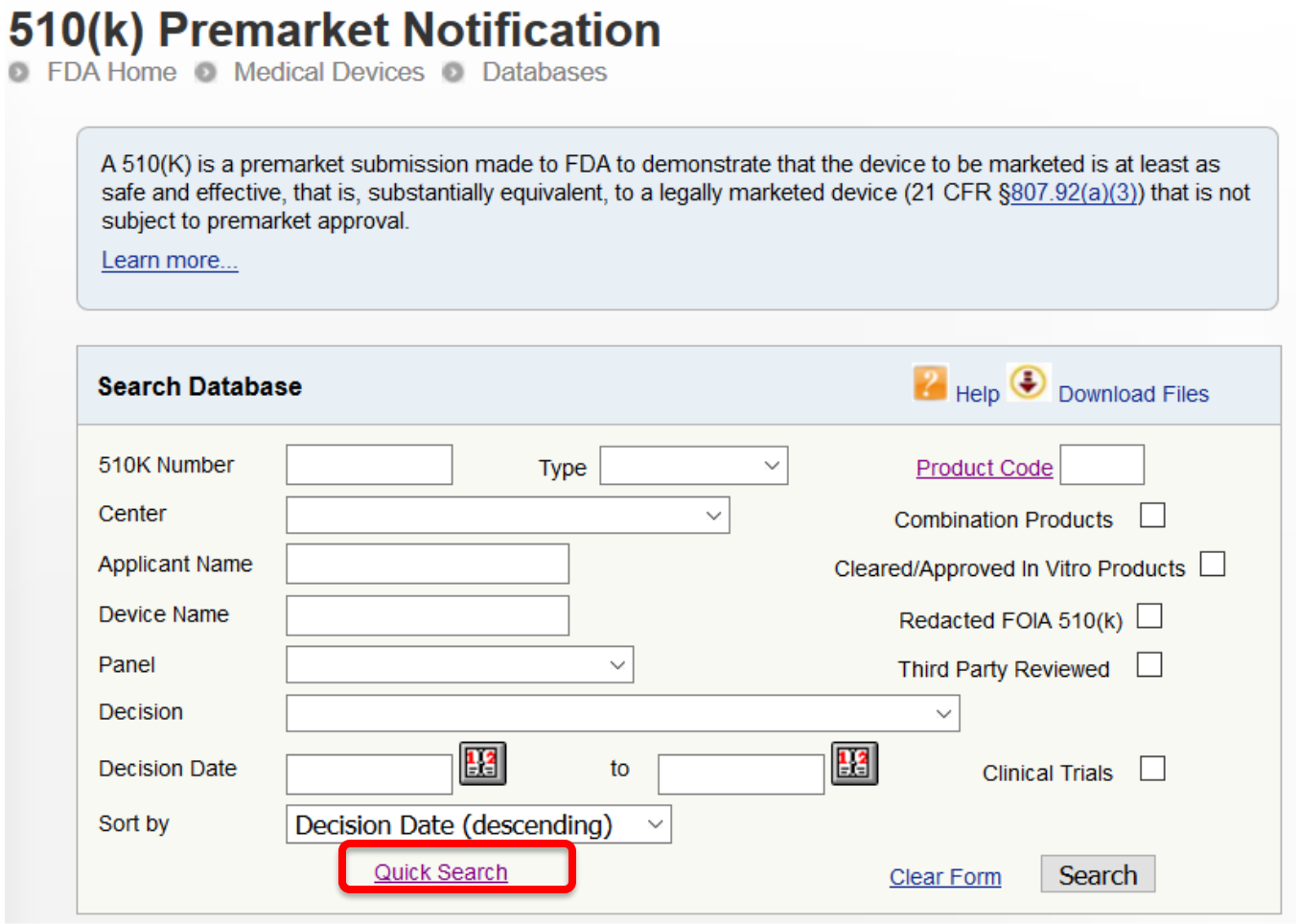
Product Code

Regulation Number & Device Class

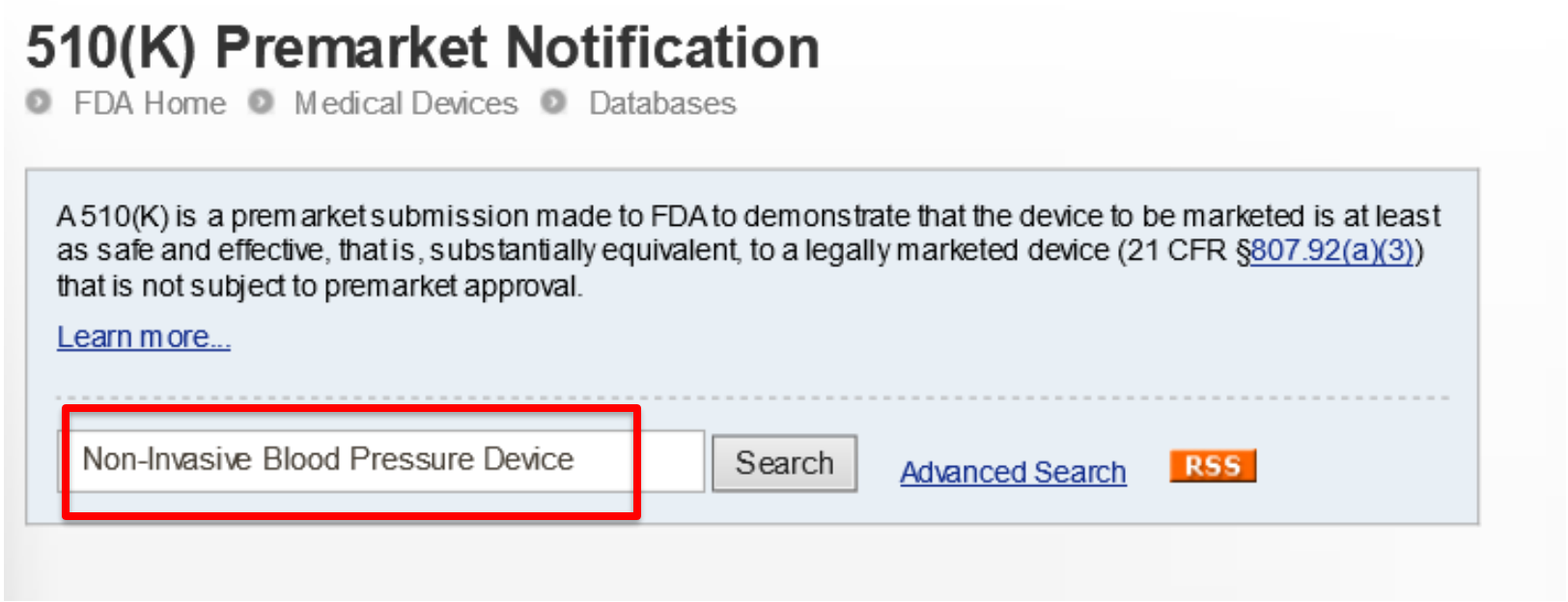
Method 2: Search for Device by clearance/approval

- **510(k) Clearance**
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- **PMA Approval**
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
- De Novo Database
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm

Method 2: Search by 510(k) Clearance



Method 2: Search by 510(k) Clearance



Method 2: Search by 510(k) Clearance

510(K) Premarket Notification

FDA Home › Medical Devices › Databases

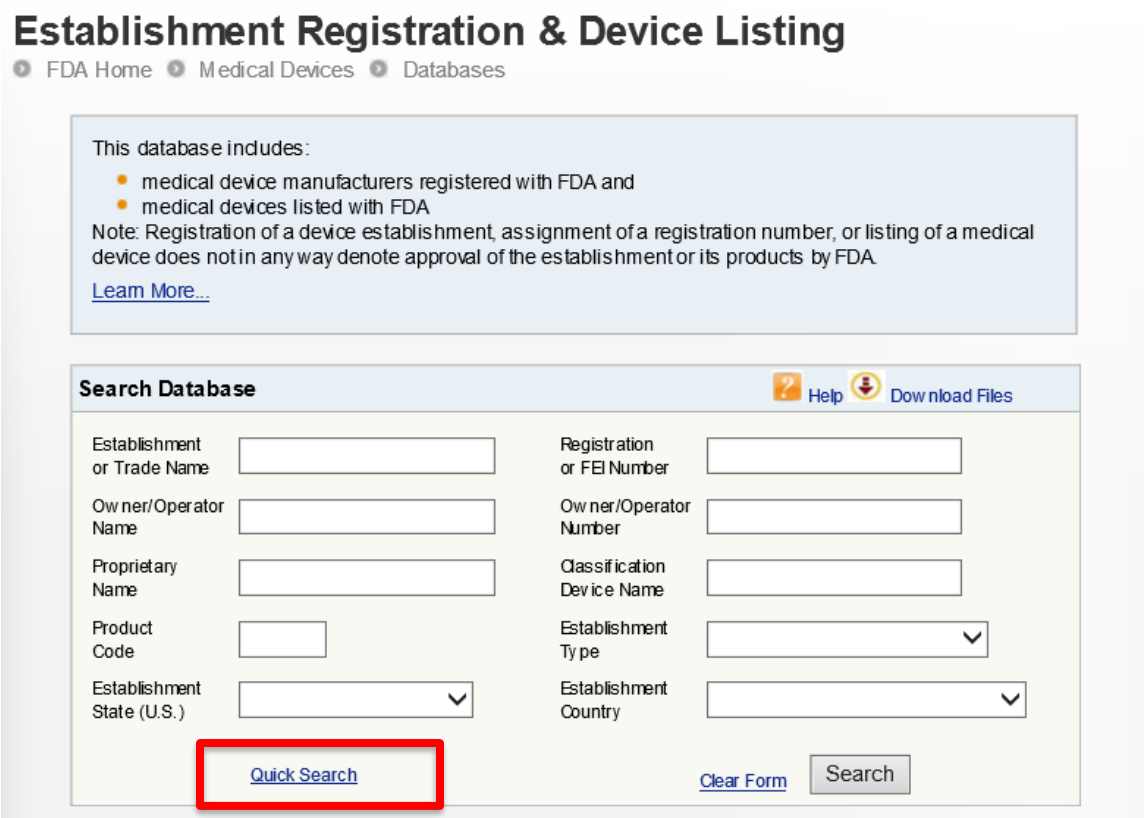
1 to 4 of 4 Results
for *Non-Invasive Blood Pressure Device*

10 results per page

New Search | Export To Excel | Help

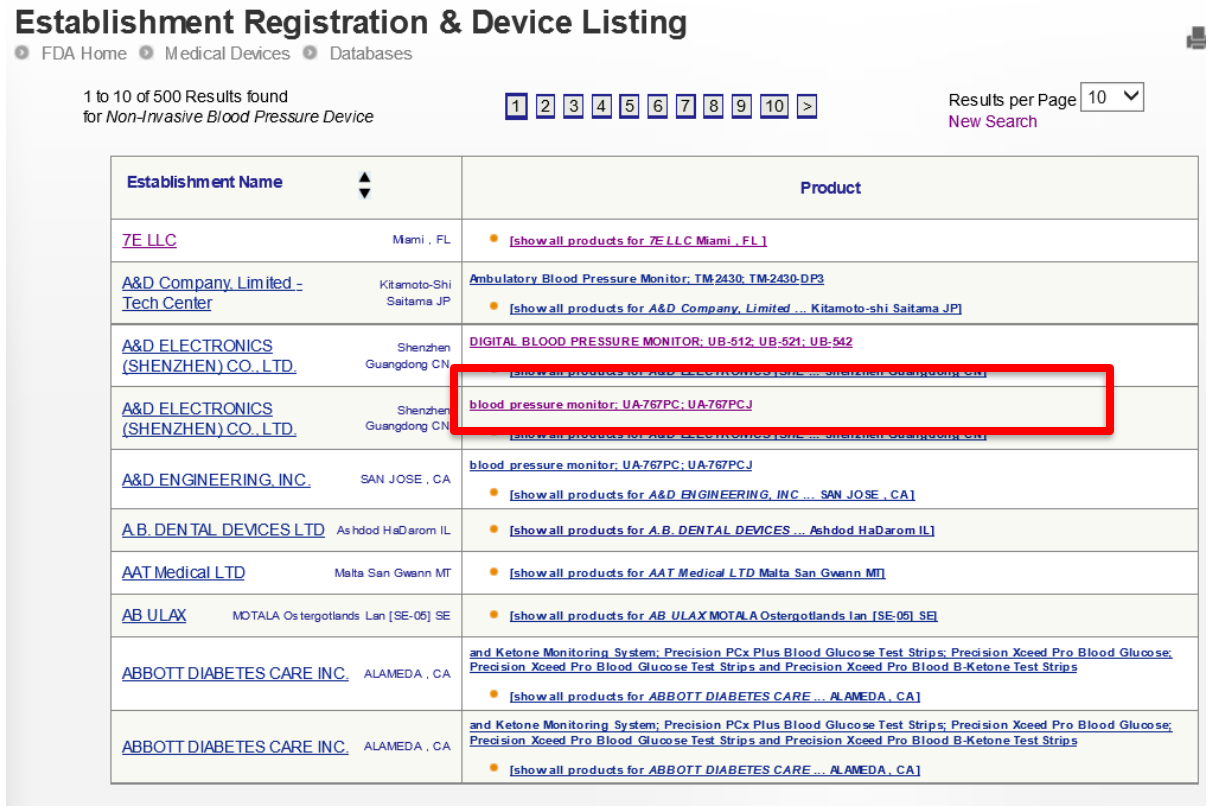
Device Name	Applicant	510(K) Number	Decision Date
Welch Allyn Non Invasive Blood Pressure (Nibp) Device	WELCH ALLYN, INC.	K093907	04/14/2010
TI-300 T-Line Non-Invasive Blood Pressure Monitoring System	United States GTM Medical Devices, Inc.	K123446	12/07/2012
Non-Invasive Hemodynamic Blood Pressure Monitor	Vita-Course Technologies Co., Ltd.	K190893	08/07/2019
Monitor, Non-Invasive Blood Pressure	AUTOMATED SCREENING DEVICES	K782000	12/05/1978

Method 3:
Search Device Listing Database



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

Method 3:
Search Device Listing Database



Establishment Registration & Device Listing

FDA Home ▸ Medical Devices ▸ Databases

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 10
New Search

Establishment Name		Product
7E LLC	Miami , FL	[show all products for *7E LLC* Miami , FL]
A&D Company, Limited - Tech Center	Kitamoto-Shi Saitama JP	Ambulatory Blood Pressure Monitor; TM-2430; TM-2430-DP3 [show all products for *A&D Company, Limited* ... Kitamoto-shi Saitama JP]
A&D ELECTRONICS (SHENZHEN) CO., LTD.	Shenzhen Guangdong CN	DIGITAL BLOOD PRESSURE MONITOR; UB-512; UB-521; UB-542 [show all products for A&D ELECTRONICS [SHE ... Shenzhen Guangdong CN]
A&D ELECTRONICS (SHENZHEN) CO., LTD.	Shenzhen Guangdong CN	blood pressure monitor; UA-767PC; UA-767PCJ [show all products for A&D ELECTRONICS [SHE ... Shenzhen Guangdong CN]
A&D ENGINEERING, INC.	SAN JOSE , CA	blood pressure monitor; UA-767PC; UA-767PCJ [show all products for *A&D ENGINEERING, INC* ... SAN JOSE , CA]
A.B. DENTAL DEVICES LTD	Ashdod HaDarom IL	[show all products for *A.B. DENTAL DEVICES* ... Ashdod HaDarom IL]
AAT Medical LTD	Malta San Gwann MT	[show all products for *AAT Medical LTD* Malta San Gwann MT]
AB ULAX	MOTALA Ostergotlands Lan [SE-05] SE	[show all products for *AB ULAX* MOTALA Ostergotlands lan [SE-05] SE]
ABBOTT DIABETES CARE INC.	ALAMEDA , CA	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 [show all products for *ABBOTT DIABETES CARE* ... ALAMEDA , CA]
ABBOTT DIABETES CARE INC.	ALAMEDA , CA	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 [show all products for *ABBOTT DIABETES CARE* ... ALAMEDA , CA]

Method 3:

New Search | Back To Search Results

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

www.fda.gov