Fifth Anniversary Meeting

Internal Session

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE

MEDICAL TECHNOLOGY SECTOR

5 ANNIVERSARY

08 May 2025

IACRC Metrics for Authorization Timelines

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“If you can’t measure it, you can’t manage it” – Peter Drucker

- Performance measurement and communication are of essence for: public administration, transparency, predictability, planning, legal compliance
- Most National Regulatory Authorities (NRAs) in the Western Hemisphere either do not measure or publish NRA metrics for medical devices
- NRAs that measure and publish use different methodologies and formats
- Not all medtech trade associations consistently capture metrics from their members
- Medtech trade associations do not currently have a standard methodology throughout the region
- Companies do generally measure approval times for their applications

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IACRC Metrics Proposal

- IACRC to map available metrics published by NRAs
- IACRC members agreement on a methodology to track performance of critical processes by NRAs:
  - NRA public performance data
  - NRA type of public data
  - Medtech association data
  - Company data
- IACRC to compile, analyze and publish the report on a quarterly basis
- Report to be used as a tool to:
  - Have a common IACRC, association, company metric and data
  - Provide visibility to Top Management on outcomes of the RA Teams + IACRC
  - Promote transparency and performance improvements with NRAs
  - Have a common metric with which to capture and report regulatory improvements to medtech management and governments

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Initial Proposal - Data

Information gathering: MS Excel

Information compilation and analysis – MS Access

Country	Period	New registration									
		Class I		Class II		Class III		Class IV		Total	
		Quantity	Avg. approval time (days)	Quantity	Avg. approval time (days)	Quantity	Avg. approval time (days)	Quantity	Avg. approval time (days)	Quantity	Avg. approval time (days)

Good Manufacturing Practices Certification			
Issuance timeframes			
Avg. Issuance time (days)	Issuance Pathway		
	NRA inspection	MDSAP	ISO 13485

Progress report

Data collection

- High complexity: great diversity (quali-auentitative) of data
- Public databases – raw data
- Analytical tools: Excel
- Delivery of data by Trade Associations or companies

Identification of stakeholders needs: NRAs, RA teams, CEOs

Data reporting

- First mockup of aggregated data

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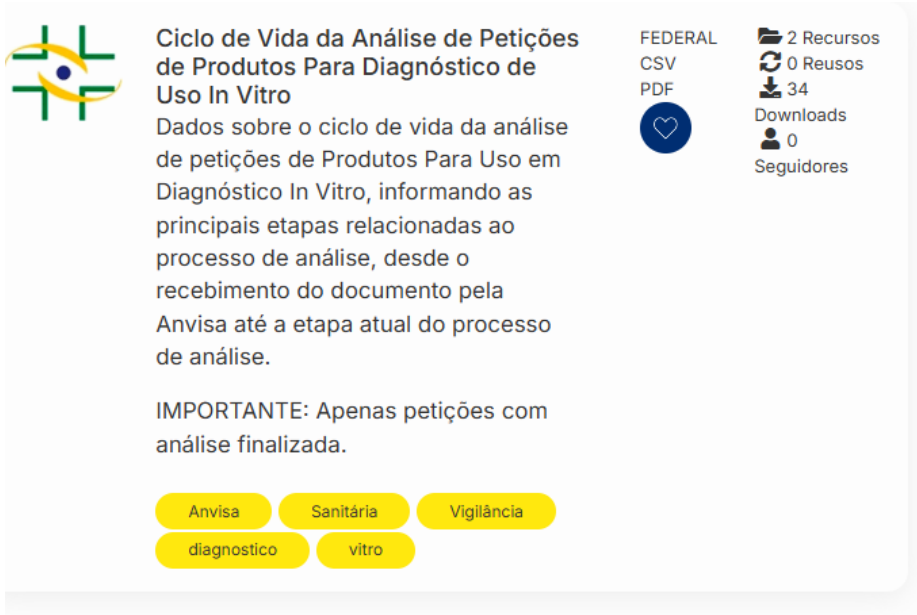
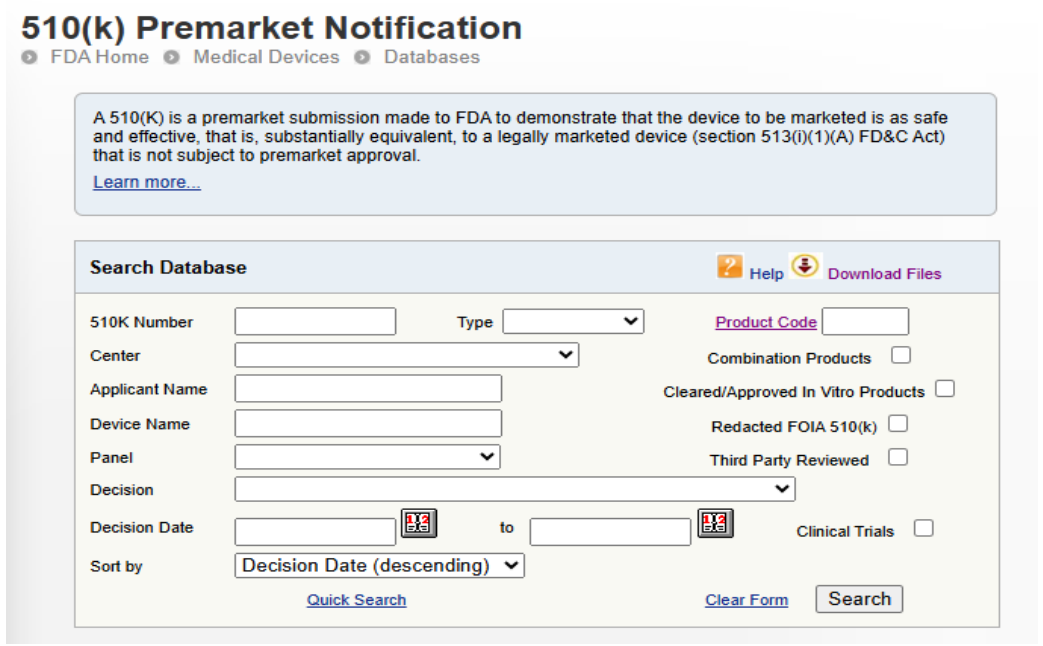
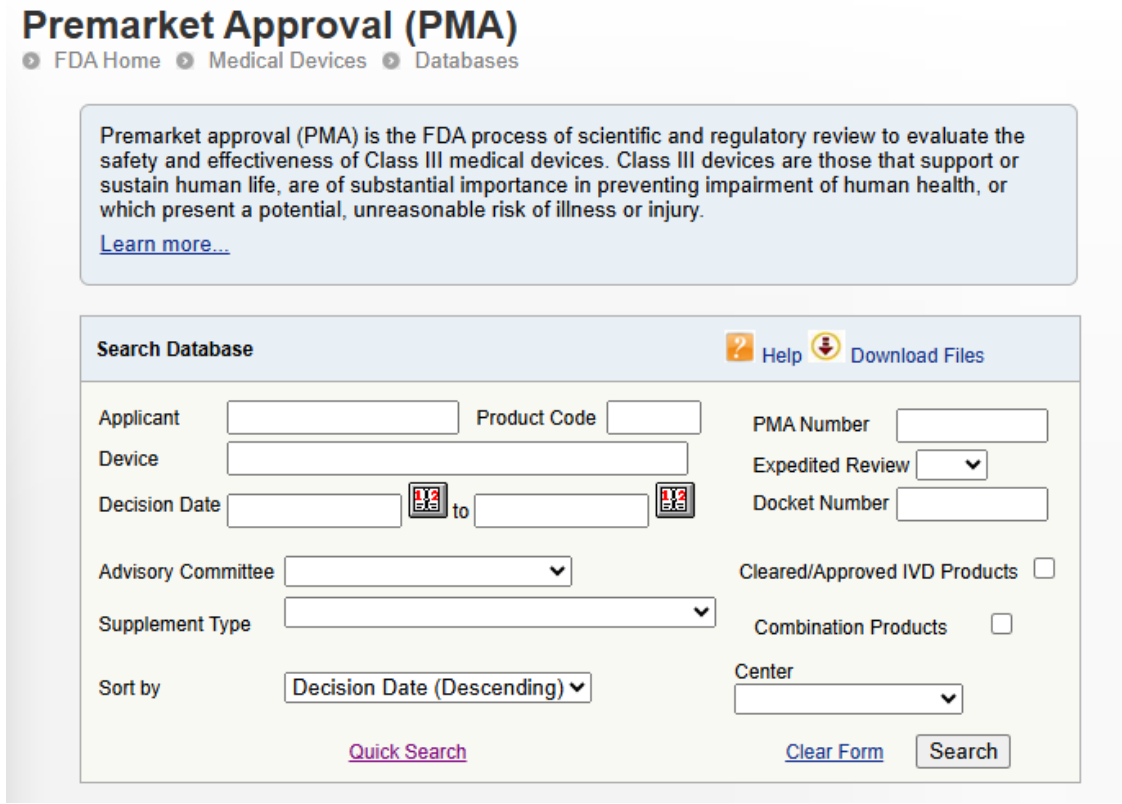
Anvisa - Life cycle of petition analysis



US FDA Database





IACRC – Consolidated timeliness

IACRC Aggregated Assessment of Timelines (Days) Consolidated A

	New Product		Changes		Comments
	Higher-Risk	Lower-Risk	Higher-Risk	Lower-Risk	
Country	(Days)	(Days)	(Days)	(Days)	
Argentina	143	49	77	34	Information provided by two companies: 1 Agile + non-agile pathway for changes
Brazil	370	69	135	38	Higher risk - Class III and IV - Average IVD & MD , Lower Risk - Class I and II - Public ANVISA Database
Canada					
Colombia	241	45	45	45	Information provided by two companies
Costa Rica	332	332	185	185	Information provided by two companies
Ecuador	128	120	105	105	Information provided by two companies
Mexico	103	68	92	66	Information provided by AMID 2024 - 2025
Peru	195	165	150	91	Information provided by two companies
U.S.	404	159	250	47	Higher Risk - Class III - Lower Risk - Class I and II - Public FDA Database
Region	239	126	130	76	

*Risk that the change poses to health

IACRC – Consolidated timeliness

IACRC Aggregated Assessment of Timelines (Days) Consolidated B

	New Product		Changes		Comments
	Higher-Risk	Lower-Risk	Higher-Risk	Lower-Risk	
Country	(Days)	(Days)	(Days)	(Days)	
Argentina	143	49	77	34	Information provided by two companies: 1 Agile + non-agile pathway for changes
Brazil	370	69	135	38	Higher risk - Class III and IV - Average IVD & MD , Lower Risk - Class I and II - Public ANVISA Database
Canada					
Colombia	241	45	45	45	Information provided by two companies
Costa Rica	332	332	185	185	Information provided by two companies
Ecuador	128	120	105	105	Information provided by two companies
Mexico	461	413	388	324	Information provided by AMID 2023 - 2024
Peru	195	165	150	91	Information provided by two companies
U.S.	404	159	250	47	Higher Risk - Class III - Lower Risk - Class I and II - Public FDA Database
Region	284	169	167	109	

*Risk that the change poses to health

Next Steps

1. IACRC Principal Member confirmation on data availability and accuracy of public sources of information identified by IACRC Secretariat
2. Identify member companies to provide information for countries where not available through Primary Members
3. Data gathering from Primary Members and companies – identify best possible tool
4. Data processing and publication of targeted reports to CEOs and for NRAs and RA communities

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THANK YOU

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