

# Perspective on ISO Standards and FDA Assessment of Wheelchairs

Rory A. Cooper, PhD

Distinguished Professor  
FISA Foundation - Paralyzed Veterans of America Chair  
Department of Rehabilitation Science & Technology  
Senior Research Career Scientist  
Department of Veterans Affairs



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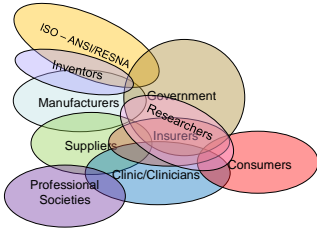
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## Wheelchair Production and Provision Is Affected by Many Agencies and Organizations



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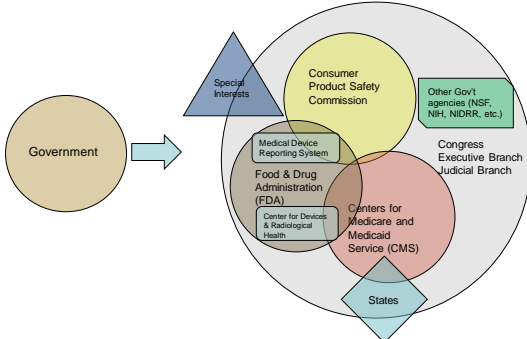
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## Government Interaction



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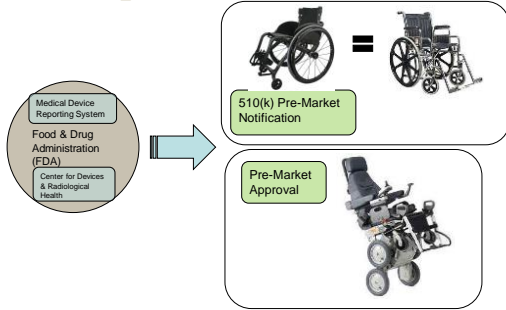
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### Simplistic View of FDA




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### FDA Definitions

#### 510(k)

A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). 510(k) (premarket notification) to FDA is required at least 90 days before marketing unless the device is exempt from 510(k) requirements.

#### PMA

Premarket Approval (PMA) is the most stringent type of device marketing application required by FDA. A PMA is an application submitted to FDA to request approval to market. Unlike premarket notification, PMA approval is to be based on a determination by FDA that the PMA contains sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective for its intended use or uses.

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/>

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### FDA Classifications




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### FDA and ISO – ANSI/RESNA Standard

- FDA may (and often does) rely on voluntary standards in its decision making process.
- ISO – ANSI/RESNA are voluntary standards that are produced and approved by a set of policies and procedures to minimize bias and to be fair.
- Testing may be performed by the manufacturer or an independent body.

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### Principles of ISO/ANSI-RESNA Standards

- Fundamental concept: Safety, efficacy, and performance.
- Repeatable, measurable, and consistent.
- Minimal criteria and reporting.
- Labeling and notification.




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### ISO – ANSI/RESNA Testing Equipment



Curb-Drop



Multi-Drum



Static/Impact Strength Tester

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### CMS Rulings/Regulations

- 2003 – Medicare Prescription Drug Improvement and Modernization Act (MMA).
  - Expanded types of health professional who may order certain types of powered mobility devices (PMD).
  - Required face-to-face examination of the beneficiary by the prescribing physician.
  - New codes to give CMS broader options for payment
- 2005 – National Coverage Determination for Mobility Assist Equipment (MAE)
  - Function based criteria algorithm called “Clinical Criteria for MAE Coverage”.

[https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/PMDFactSheet07\\_Quark19.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/PMDFactSheet07_Quark19.pdf)

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### CMS Codes for Manual Wheelchairs



K0001- Standard



K0002- Standard Hemi



K0003- Lightweight



K0005- Ultra Lightweight



K0004- Lightweight

<http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/QualityStandardsK0005Wheelchairs.pdf>

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### CMS Codes for Power Wheelchairs



Group 1



Group 2



Group 3



Group 4

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## Key Concepts

- Several federal, state, and private agencies are involved in the process of inventing, producing and providing wheelchairs.
- FDA, CPSC and CMS all communicate and influence regulations and guidelines for wheelchairs.
- FDA, CPSC, and CMS view wheelchairs differently.
- Manufacturers and distributors use different messages depending on the audience – sometimes adding to the confusion.

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