Management, Compliance with Regulatory Requirements for Design of Medical Devices

10.1 INTRODUCTION

The first step in the process is to make absolutely sure that the product that you intend to market is a medical device

A MEDICAL DEVICE: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them
- **Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals**, or
- Intended to affect the structure or any function of the body of man or other animals, and **which does not achieve any of it's primary intended purposes through chemical action** within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes

10.2 DEVICE CLASSIFICATION

Medical devices are classified and regulated according to their degree of risk to the public.

- US class I, II and III vs. Canada I, II, III, IV
- US Class I is lowest risk, Class III is highest
- Determining the classification is the first step in obtaining FDA clearance

/approval, if required

10.2.1 Device Product Codes

- CFR Title 21 -Food and Drugs: Parts 862 to 892
- 862 Clinical chemistry and clinical toxicology devices
- 864 Hematology and pathology devices
- 866 Immunology and microbiology devices
- 868 Anesthesiology devices
- 870 Cardiovascular devices
- 872 Dental devices
- 874 Ear, nose, and throat devices
- 876 Gastroenterology-urology devices
- 878 General and plastic surgery devices
- 880 General hospital and personal use devices
- 882 Neurological devices
- 884 Obstetrical and gynecological devices
- 886 Ophthalmic devices
- 888 Orthopedic devices
- 890 Physical medicine devices
- 892 Radiology devices

10.2.2 CLASS I DEVICES

- Present the least risk, minimal potential for harm and simple design
- Most Class 1 Devices are exempt from Premarket Notification [(510(k)], in those cases no product information needs to be submitted to FDA prior to commercialization
- Establishment Registration and Device Listing is required at the time of commercialization for ALL device classes
- **Examples:** elastic bandages, examination gloves, and oxygen masks, inflatable extremity splint, line Isolation monitor, intra-oral dental drill, powered toothbrush

10.2.3 CLASS II DEVICES

- Present a greater concern –technology is understood but needs data regarding performance. Clearance is based on substantial equivalence to a predicate
- **Subject to controls**
  - Controls may include special labeling requirements, mandatory performance standards, and post-market surveillance

- **Examples:** power wheelchairs, infusion pumps, and surgical instruments specific to the implant, nebulizer cardiac monitor, hemodialysis system, electro-surgical cutting & coagulation device, surgical Laser for dermatology use

10.2.4 CLASS III DEVICES

- Highest risk devices, represent new technology – less than 10% of devices
- Subject to more stringent controls, bench & animal studies, human clinical data, submission of Premarket Approval Application (PMA) & review by outside panel
- FDA must determine that the PMA contains sufficient valid scientific evidence

to assure that the device is safe and effective for its intended use(s)

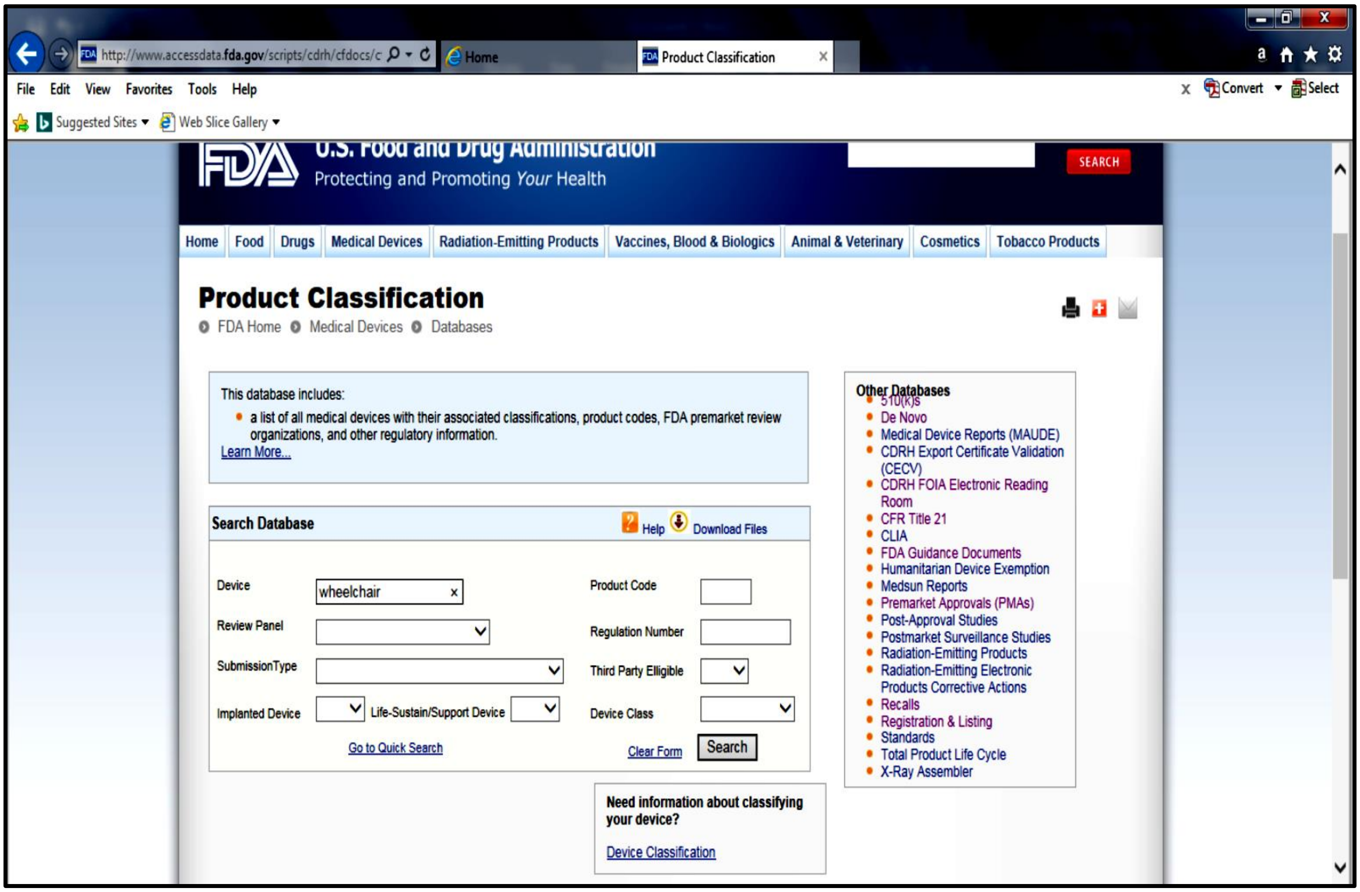
- **Examples:** heart valves, hearing aids, hip implants, CT scanners, lasers, computerized microscopes, cardiac stents, retinal implants, Cardiovascular Stent, Intra-Aortic Ballon Implanted Urinary Continence Device, Implantable Diaphragmatic/Phrenic Nerve Stimulator, Membrane Lung for Long Term Pulmonary Support

10.3 DEVELOPING A REGULATORY STRATEGY

- Describe the device
- What is the intended use of the device?
- What is the environment of use?
- What category does the device fit into? (21CFR Parts 862-892)
- What Class is the device? (Class I, II, or III)
- What is the product code?
- What are the submission requirements?
- Are similar products available on the market? (predicate device)
- Are there applicable Standards or Guidance Documents?
- Which countries are targeted?

Ex: ACME WHEELCHAIR COMPANY

- Acme Wheelchair Company
- New power wheelchair
- Classification, pro code?
- Regulatory requirements?
  - Bench testing
  - Labeling
- Guidance document?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U.S. Food and Drug Administration
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SEARCH
Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products
Product Classification
FDA Home Medical Devices Databases
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...
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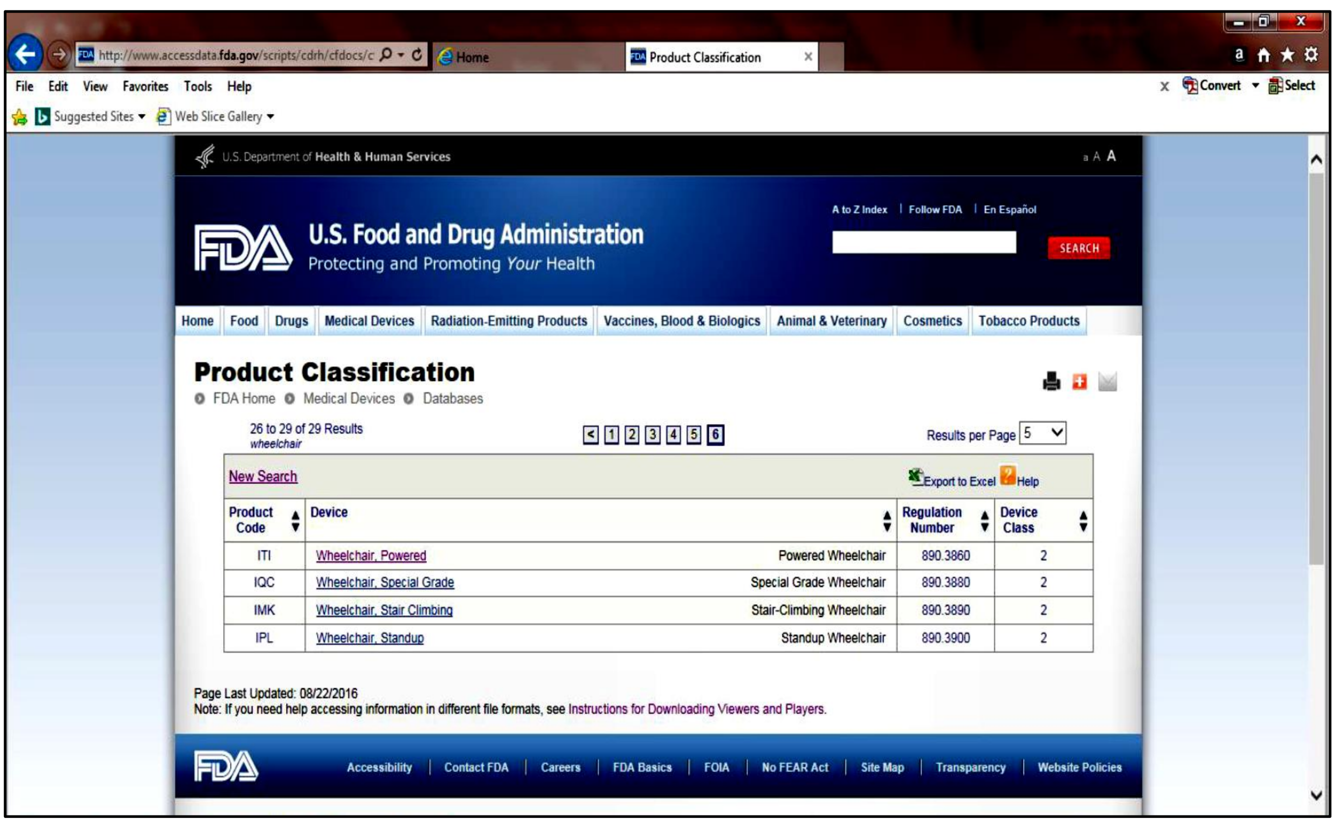
Device
wheelchair
Product Code
Review Panel
Regulation Number
SubmissionType
Third Party Eligible
Implanted Device
Life-Sustain/Support Device
Device Class
Go to Quick Search
Clear Form
Search
Need information about classifying your device?
Device Classification
Other Databases
510(k)s
De Novo
Medical Device Reports (MAUDE)
CDRH Export Certificate Validation (CECV)
CDRH FOIA Electronic Reading Room
CFR Title 21
CLIA
FDA Guidance Documents
Humanitarian Device Exemption
Medsun Reports
Premarket Approvals (PMAs)
Post-Approval Studies
Postmarket Surveillance Studies
Radiation-Emitting Products
Radiation-Emitting Electronic Products Corrective Actions
Recalls
Registration & Listing
Standards
Total Product Life Cycle
X-Ray Assembler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Product Classification
FDA Home Medical Devices Databases
26 to 29 of 29 Results
wheelchair
1 2 3 4 5 6
Results per Page 5
New Search
Export to Excel
Help
Product Code
Device
Regulation Number
Device Class
ITI Wheelchair, Powered Powered Wheelchair 890.3860 2
IQC Wheelchair, Special Grade Special Grade Wheelchair 890.3880 2
IMK Wheelchair, Stair Climbing Stair-Climbing Wheelchair 890.3890 2
IPL Wheelchair, Standup Standup Wheelchair 890.3900 2
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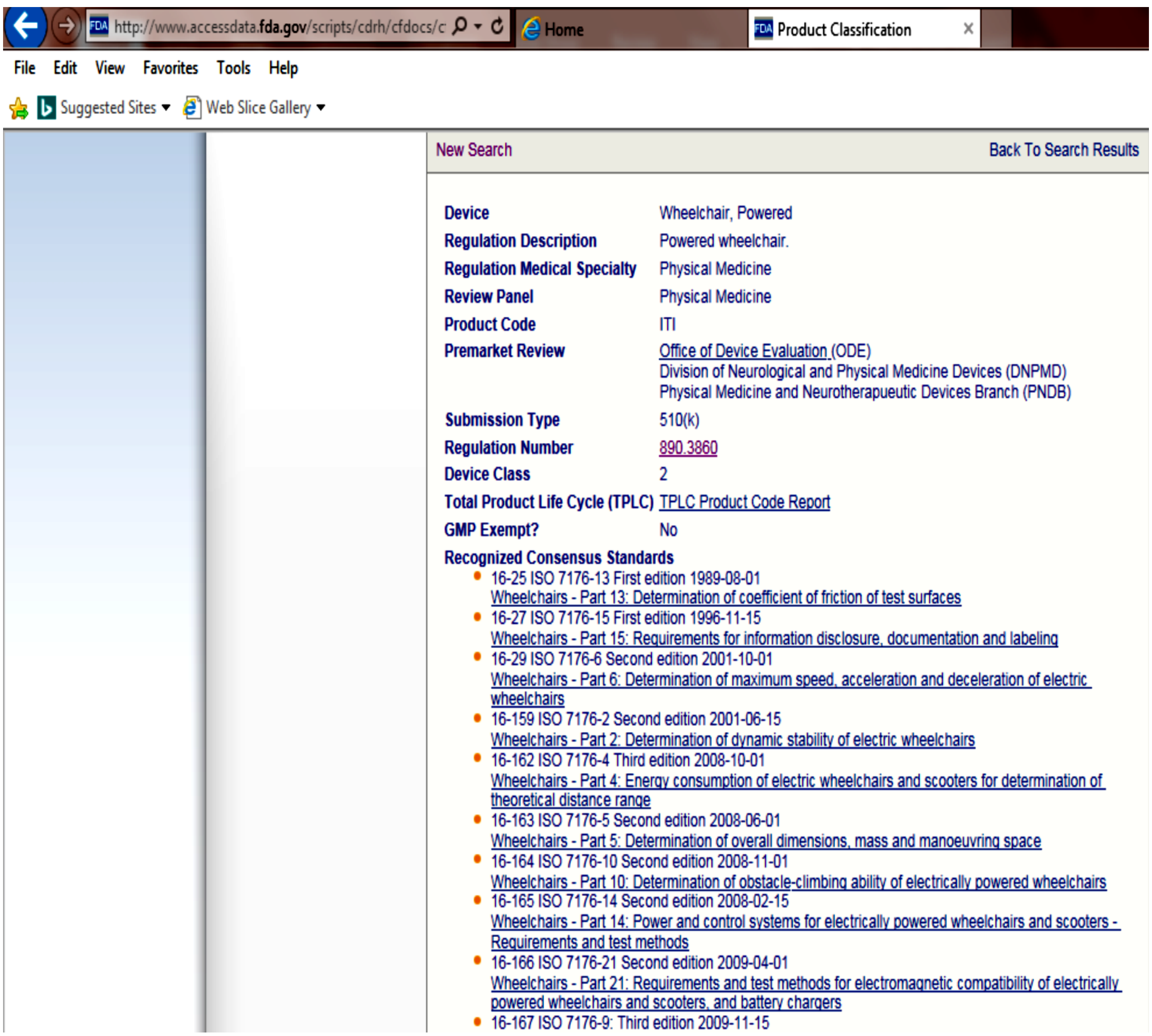
- Powered wheelchair
- Physical Medicine Branch
- 21 CFR 890.3860

Sec. 890.3860 Powered wheelchair.

(a) Identification. A powered wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

(b) Classification. Class II (performance standards).



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Device	Wheelchair, Powered
Regulation Description	Powered wheelchair.
Regulation Medical Specialty	Physical Medicine
Review Panel	Physical Medicine
Product Code	ITI
Premarket Review	Office of Device Evaluation (ODE) Division of Neurological and Physical Medicine Devices (DNPMD) Physical Medicine and Neurotherapeutic Devices Branch (PNDB)
Submission Type	510(k)
Regulation Number	890.3860
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Recognized Consensus Standards

- 16-25 ISO 7176-13 First edition 1989-08-01
  Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
- 16-27 ISO 7176-15 First edition 1996-11-15
  Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
- 16-29 ISO 7176-6 Second edition 2001-10-01
  Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs
- 16-159 ISO 7176-2 Second edition 2001-06-15
  Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs
- 16-162 ISO 7176-4 Third edition 2008-10-01
  Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
- 16-163 ISO 7176-5 Second edition 2008-06-01
  Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space
- 16-164 ISO 7176-10 Second edition 2008-11-01
  Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
- 16-165 ISO 7176-14 Second edition 2008-02-15
  Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
- 16-166 ISO 7176-21 Second edition 2009-04-01
  Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
- 16-167 ISO 7176-9: Third edition 2009-11-15

American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for
Wheelchairs (including Scooters) Section 26: Vocabulary

- 16-190 ISO 7176-11 Second edition 2012-12-01
  Wheelchairs - Part 11: Test dummies
- 16-191 ISO 7176-16 Second edition 2012-12-01
  Wheelchairs - Part 16: Resistance to ignition of postural support devices
- 16-192 ISO 7176-3 Third edition 2012-12-15
  Wheelchairs - Part 3: Determination of effectiveness of brakes
- 16-193 ASME A18.1-2014
  Safety Standard for Platform Lifts and Stairway Chairlifts
- 16-194 ISO 7176-25 First edition 2013-07-15
  Wheelchairs Part 25: Batteries and chargers for powered wheelchairs
- 16-195 ISO 7176-1 Third edition 2014-10-01
  Wheelchairs - Part 1: Determination of static stability
- 16-196 ISO 7176-7 First Edition 1998-05-15
  Wheelchairs - Part 7: Measurement of seating and wheel dimensions
- 16-197 ISO 7176-8 Second Eiditon 2014-12-15
  Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths
- 16-198 ISO 7176-22 Second Edition 2014-09-01
  Wheelchairs - Part 22: Set-up procedures

Guidance Document

- Guidance Document for the Preparation of Premarket Notification [510k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles

Implanted Device? No

Life-Sustain/Support Device? No

Third Party Review

- Eligible for *Accredited Persons Program*

Accredited Persons

- Bsi Healthcare
- Center For Measurement Standards Of Industrial
- Dekra Certification B.v.
- Regulatory Technology Services, Llc
- Third Party Review Group, Llc
- Tuv Sud America Inc.

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10.4 CLASS II REQUIREMENTS

FDA REGULATORY 101/ 510(k) Requirements

- Basis of 510(k) is comparison to another legally marketed device
- A device is substantially equivalent if, in comparison to a predicate it:
  - has the same intended use as the predicate; and
  - has the same technological characteristics as the predicate; or
  - has the same intended use as the predicate; and
  - has different technological characteristics and the information submitted to FDA;
  - does not raise new questions of safety and effectiveness; and
  - demonstrates that the device is at least as safe and effective as the legally marketed device.

10.4.1 PREDICATE DEVICE

- Search 510(k) database
    - 510(k) Summary
- Competitor websites
- Own device—moving to 2ndgeneration

10.4.2 REGULATORY PLAN

- R&D will have a project plan, Regulatory should have their own detailed plan and timeline
    - Review requirements with the team (check previous submission, predicates, guidance documents)
    - Obtain SharePoint or Dropbox site to share with the team
    - Create folders
    - Draft and complete each section
    - Ensure Substantial Equivalent arguments are reviewed by the team early and that they are clear and concise
    - Review and approval of the completed submission
    - Administration**:** printing, binding and submitting

10.4.3 510(k) ELEMENTS

- Truthful and Accuracy Statement
- Executive Summary
- Device Description
- Indication for Use Statement
- Substantial Equivalence Discussion
- Proposed labeling
- Sterilization and Shelf Life
- Biocompatibility

- Electromagnetic Compatibility and Electrical Safety
- Performance Testing
  - Animal
  - Bench
  - Clinical
- Software
- 510(k) Summary

Useful Information

- FDA Home Page - www.fda.gov
- FDA Device Advice - www.fda.gov/cdrh/devadvice
- Guidance Documents
  - www.fda/gov/MedicalDevices/DeviceRegulationandGuidance/Guidance Documents
- Medical Device Databases
  - www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Database

11.1 DESIGN ASSURANCE // FDA REGULATORY 101

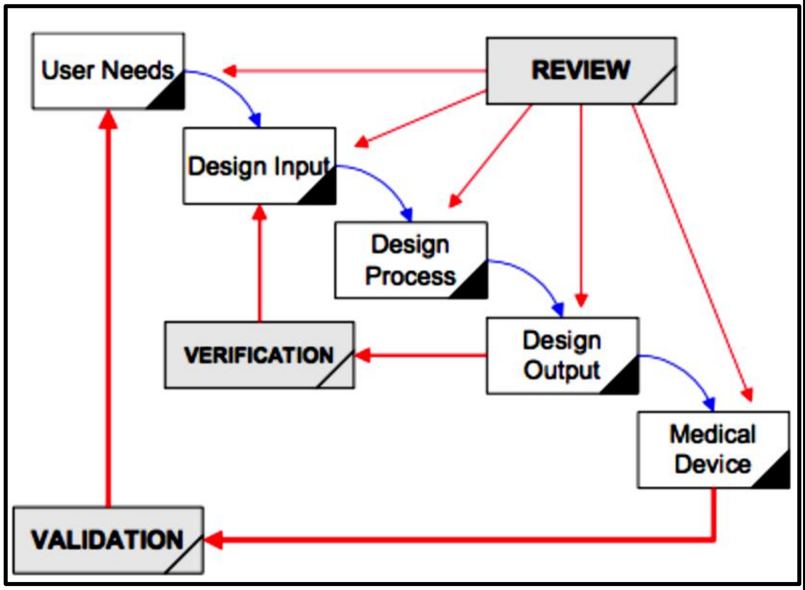
11.1.1 DESIGN ASSURANCE REQUIREMENTS

- Once device design has been frozen, design controls must be followed
- Before bench testing is initiated and documentation developed to support the 510(k), design inputs, design outputs, risk management activities, etc. must be evaluated and documented
- Basic Quality System

11.1.2 DESIGN ASSURANCE

- Design Controls –What are they?
- A set of quality practices and procedures incorporated into the design and development process

- Control the design process to assure that device specifications meet:
- User needs
- Intended use



11.2 Types of Design Inputs

- Intended Use
- User Needs
- Physical/ chemical characteristics
- Performance requirements
- Safety
- Reliability
- Environmental limits
- User interfaces
- Regulatory requirements
- Labeling
- Human factors
- Maintenance
- Compatibility with other devices
- Sterilization
- Energy source
- Toxicity and biocompatibility

11.3 ACME WHEELCHAIR COMPANY

11.3.1 Design Inputs:

- Power Wheelchair
- Product Requirements
- User weight limit 350 lbs.
- Dimensional requirements
- Battery life 18 hours
- Home use and outdoors
- Labeling requirements

11.3.2 Design Output –820.30(d)

- Design output are the design specifications which should meet design input requirements, as confirmed during design verification and validation and ensured during design review
- The output includes the device, its labeling and packaging, associated specifications and drawings, and production and quality assurance specifications and procedures
- Design outputs must contain and/or make reference to "acceptance criteria" essential for proper functioning of the device
- Tests are NOT Design Outputs

11.3.3 Design Outputs: (ACME WHEELCHAIR COMPANY)

Power Wheelchair

Product Requirements

- Verification testing confirms 350 lb. weight limit; meets ISO standard for dimensions, mass, maneuvering space and climatic testing for power wheelchairs

- User manual operating instructions, warning labels warn against use in excessive temperatures

11.3.4 Design Verification –820.30(f)

- Did I make the product right? (i.e. specified requirements have been fulfilled)
- Confirm design output meets design input requirements
- Types of verification activities include:
  - Inspections
  - Tests
  - Analysis

11.3.5 Design Validation –820.30(g)

- Did I make the right product? (i.e. device specifications conform with the user needs and intended use(s))
- Perform design validation:
  - Conform to defined user needs and intended uses
  - Under actual or simulated use conditions
  - Under defined operating conditions
  - On initial production units, lots, or batched or their equivalents
  - Includes software validation and risk analysis, where appropriate

11.3.6 Human Factors/Usability Engineering (ISO/IEC62366)

(~1/3 of the approximately 100,000 MDRs filed each year mention use error)

- Task Analysis
  - Critical Functions
  - Use Cases
  - User populations (age, gender, educational level, etc.)
  - Environment of Use (hospital, care facility, doctor's office, home)
- Formative User Evaluation (Verification)

- Summative User Evaluation (Validation)
  - Acquire information from the Device
  - Manipulate and Maintain the Device
  - Under stand the Labeling

11.3.7 Risk Management (ISO-14971)

- Identify potential risks / hazards:
  - Product Defects– Design/ Manufacturing
  - Side Effects– (Un) avoidable (un) known side effects associated with use
  - User Errors– Healthcare professional, patient, care giver
- Analyze the causes
- Evaluate probability and severity of risks
- Eliminate or mitigate the risk
  - Redesign
  - Test o inspection
  - Labeling (Instructions / Warnings)
- Re-evaluate the residual risk

11.4 Postmarket Activities / FDA REGULATORY 101 SERIES

11.4.1 REGISTRATION AND LISTING

- Spec developers, manufacturers, contract manufacturers and others must register their facility and pay user fee
- List their devices
- Update at least yearly

11.4.2 MEDICAL DEVICE REPORTING

- Medical Device Reporting (MDR) one of the post-market surveillance tools

the FDA uses to
  - monitor device performance
  - detect potential device-related safety issues, and
  - contribute to benefit-risk assessments of these products
- 21 CFR 803 -Required to have written MDR procedures that provide for:
  - Timely and effective identification, communication, and evaluation of events that may be MDR reportable.

11.4.3 FDA INSPECTIONS

- The FDA is mandated by law to inspect manufacturers of class II and class III devices at least once every 2 years.
- In addition, all PMAs and 510(k) clearances for class III devices are contingent on completion of a satisfactory facility inspection.
- Other factors that can initiate an inspection include audit of clinical investigators, recalls, enforcement actions, complaints of serous problems or significant Medical Device Reports (MDRs).

11.5 Novel Technology / FDA REGULATORY 101 SERIES

11.5.1 DEVICE CLASSICATION

What if I am unsure of classification or FDA requirements for my device?

- Obtain a detailed regulatory strategy from an expert
- Request designation from FDA via the 513g process
- Request a Pre-submission meeting with FDA
- Follow the pathway for an existing commercial device
- Consider a progressive regulatory pathway

11.5.2 PRE-SUBMISSION MEETING

- Pre-Submission Meeting recommended

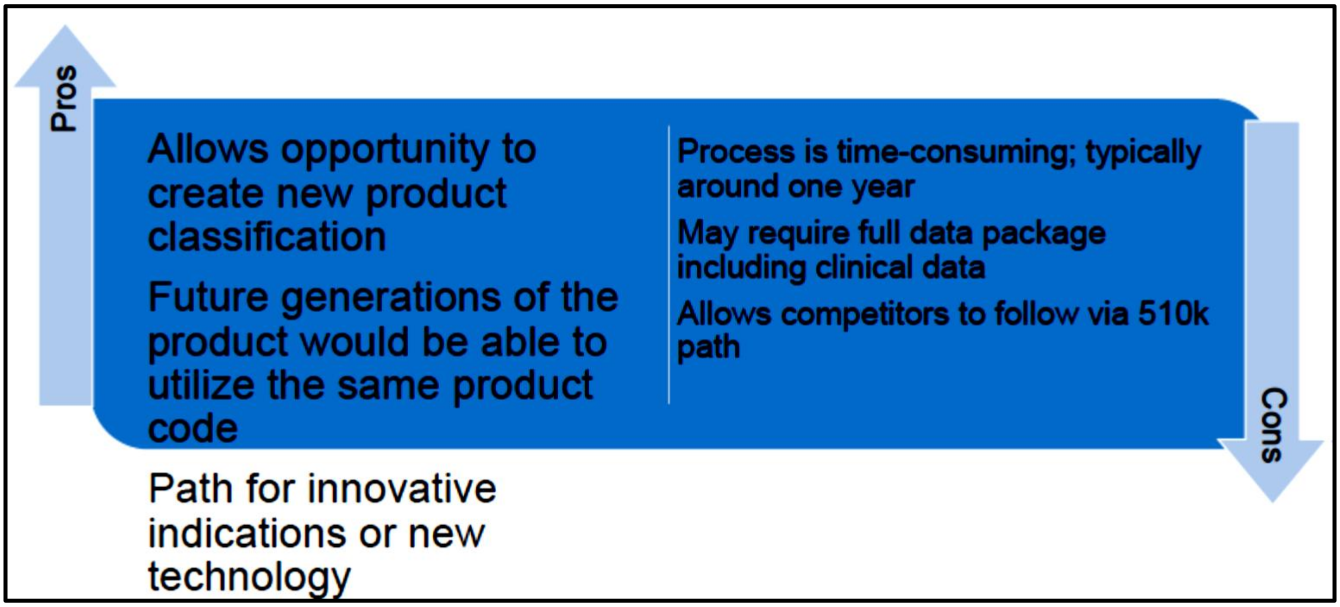
  - Novel technology
  - New indications, product claims
  - De Novo, IDE, PMA
  - Previous NSE or withdrawn 510(k) for the same device
  - Prior to completing clinical trial for input on protocol
- Pre-Submission Meeting
  - Early FDA feedback
  - Regulatory strategy confirmed
  - Preclinical or clinical study protocols
- Meeting preference
  - Face-to-face vs. teleconference
  - FDA concerns prior to meeting
- Attendees
  - Clinician helpful

11.6 DE NOVO

- "Evaluation of Automatic Class III Designation"
  - Devices not on the market before the 1976 Medical Device Amendments
  - No available predicate
  - Classified as Class III by statute, not based on level of risk they pose
- Most reclassifications occur simultaneously with clearance of the proposed device (option exists to propose reclassification followed by submission)
- Device must have a low to moderate risk profile
- Clinical data is generally required
- Pre-submission meeting recommended

- FDA agreement that no predicate exists
- Confirm adequate preclinical and clinical data to support submission
- Specific FDA concerns

11.6.1 DE NOVO PROS/CONS



11.6.2 SUCCESS

SUCCESS 510(k) CLEARANCE