A regulator’s view on medical robots: Overview of FDA's activities

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Center for Devices and Radiological Health (CDRH) Mission

Getting **safe and effective** medical devices to market as quickly as possible...

...while ensuring that medical devices and radiological products currently on the market remain **safe and effective**.

Helping the public get science-based accurate information about medical devices & radiological products needed to improve health.
Medical Device

The Federal Food Drug & Cosmetic (FD&C) Act practically defines a medical device as any healthcare product that does not achieve its principal intended purpose by chemical action or by being metabolized.

The full definition is:

- "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 its 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."
Premarket Review

• Required when:
  o Marketing a device for the first time
  o Proposing a new intended use
  o Making changes that could significantly affect safety or effectiveness

• More than 4,000 submissions/year
Medical Device Regulation

Device Classification

- Over 1700 generic types of devices (pro codes)
- 16 medical specialties (panels)
- 3 regulatory classes / regulatory controls

Based on device

- intended use – general purpose of device
- indications for use – condition specific
- risk posed to patient or user
Classification Product Codes

- Database contains
  - 3 letter product code
  - device type
  - product classification
  - link to the Code of Federal Regulations (CFR)
- helps to delineate technology and indication subgroups within a regulation
Medical Specialties

- Chemistry and Toxicology
- Hematology and Pathology
- Immunology and Microbiology
- Anesthesiology
- Cardiovascular
- Dental
- Ear, Nose, and Throat
- Gastroenterology and Urology
- General and Plastic Surgery

- General Hospital and Personal Use
- Neurological
- Obstetrical and Gynecological
- Ophthalmic
- Orthopedic
- Physical Medicine
- Radiology
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**International Workshop on Medical Robots**
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Limitations of exemptions

Exceeded when the new Class I or II device compared to others of that generic type:

• has different intended use
• uses different fundamental **scientific technology**

Example

• surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade
Substantially Equivalent

A device is substantially equivalent to a predicate if:

- intended use
  - device = predicate
- technological characteristics
  - device = predicate or
  - if device ≠ predicate
    - no new types of questions of safety and effectiveness and
    - reasonable assurance at least as safe and effective as the predicate

About 3% of 510(k) submissions are not substantially equivalent
Elements of 510(k) submission

Elements include:

- Indications for Use Statement
- Declarations of Conformity
- Device Description
- Substantial Equivalence Discussion
- Proposed Labeling
- Sterilization/Shelf Life
- Biocompatibility
- Software
- Electromagnetic Compatibility/Electrical Safety
- Performance Testing – Bench
- Performance Testing – Animal
- Performance Testing – Clinical
Resources - Guidance

- documents represent FDA’s current thinking on subjects including
  - processing, content, and evaluation of regulatory submissions
  - design, production, manufacturing, and testing of regulated products
  - inspection and enforcement procedures
- information intended to assist CDRH staff, regulated industry and the public in understanding and complying with relevant regulations and laws
- alternative approach may be used if it satisfies the requirements
- 175 guidances published on FDA website by CDRH premarket office back to 2000
Resources - Standards

- supplement premarket review process
- conformance to recognized consensus standards can **demonstrate safety or effectiveness**

- Possible advantages:
  - simplify and streamline the premarket review process
  - reduce the amount of documentation submitted
  - shorten review time
- can be special controls for Class II devices

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**Guidance for Industry and FDA Staff**

**Recognition and Use of Consensus Standards**

Document issued on: September 17, 2007

This document supersedes the “Recognition and Use of Consensus Standards; Guidance for Industry and for FDA Staff” document issued on June 20, 2001.

For questions regarding this document contact Carol Herman at carol.herman@fda.hhs.gov or 240-276-0558.
FDA Recognized Standards

- Published in Federal Register at least 2x/year
- Searchable database on FDA website

Search by:
  - Type
    - Vertical, horizontal
    - national, international
    - test methods, and materials specifications
  - SDO
    - Top 5: 100-300+ per organization
      - ISO/IEC, ASTM, ANSI, CLSI, AAMI
  - Product Area
    - Top 5: about 100 per area
      - Radiology, Sterility, Surgery/General Hospital, InVitro Diagnostics, Materials
Application to Review of Robotic Devices
Robotic related devices cleared by FDA

- Search of “robo” “robot” or “robotic” in CDRH databases
  - Pro codes (4)
  - 510(k) (73)
  - PMA (0)
  - Listing (34)
# Robot related pro codes

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<th>Device Name</th>
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<td>system, surgical, computer controlled instrument</td>
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<td>NEQ</td>
<td>device, telemedicine, robotic</td>
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<td>II</td>
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<td>OJP</td>
<td>orthopedic computer controlled surgical system</td>
<td>Stereotaxic instrument</td>
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<td>OQQ</td>
<td>diagnostic ultrasonic transducer, robotic</td>
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Devices with Robot related pro codes

da Vinci Surgical System

- Pro Code – NAY system, surgical, computer controlled instrument
- Description – Endoscope and accessories (876.1500)
- Review Panel – General and Plastic Surgery
- Specialty – Gastroenterology/Urology
- Device Class – II
- GMP Exempt – No

www.intuitivesurgical.com
Devices with Robot related pro codes

DigiMatch Robodoc Surgical System

- Pro Code – OJP orthopedic computer controlled surgical system
- Description – Stereotaxic instrument (882.4560)
- Review Panel – Neurology
- Device Class – II
- GMP Exempt – No
- Technical method – registers patient anatomy to a pre-operative surgical plan to guide a robotic arm during the milling of the femoral canal for primary total hip arthroplasty

www.robodoc.com
Devices with Robot related pro codes

Delica TCD Digital Transcranial Doppler Ultrasound System

- Pro Code – OQQ diagnostic ultrasonic transducer, robotic
- Description – Diagnostic ultrasonic transducer (892.1570)
- Review Panel – Radiology
- Device Class – II
- GMP Exempt – No
- Technical method – Robotic component maintains signal and recovers lost signal
Listed Devices with Robot related names

Cyberknife Robotic Radiosurgery System

- Pro Code – IYE, accelerator, linear, medical
  - MUJ system, planning, radiation therapy treatment
- Description – Medical charged-particle radiation therapy system (892.5050)
- Review Panel – Radiology
- Device Class – II
- GMP Exempt – No

www.accuray.com
Listed Devices with Robot related names

ExacTrac Robotic Patient Alignment

- Pro Code – JAI, couch, radiation therapy, powered
- Description – Powered radiation therapy patient support assembly (892.5770)
- Review Panel – Radiology
- Device Class – II
- GMP Exempt – No
Listed Devices with Robot related names

iSR'obot Mona Lisa 8-axis surgical robot with ultrasound imaging (cleared not listed)

- Pro Code – IYO, system, imaging, pulsed echo, ultrasonic (and ITX transducer, ultrasonic, diagnostic)
- Description – Ultrasonic pulsed echo imaging system (892.1560)
- Review Panel – Radiology
- Device Class – II
- GMP Exempt – No
Listed Devices with Robot related names

RIO Robotic Arm Interactive Orthopedic System

- Pro Code – OLO orthopedic stereotaxic instrument
- Description – Stereotaxic instrument (882.4560)
- Review Panel – Orthopedics
- Specialty – Neurology
- Device Class – II
- GMP Exempt – No

- Technical method – User loads computer software pre-op to plan surgery procedure, then registers the patient anatomy during surgery to allow software to track patient anatomy, implants, and surgical tools in real time/space.

www.makosurgical.com
Listed Devices with Robot related names

ARTAS System
- Pro Code – ONA, computer assisted hair harvesting system
- Description – Stereotaxic instrument (882.4560)
- Review Panel – General & Plastic Surgery
- Specialty – Neurology
- Device Class – II
- GMP Exempt – No
- Technical method – computer assisted harvesting system
- Physical state – computer assisted station with needle mechanism, force sensor, robotic arm and video imaging system

www.restorationrobotics.com
Listed Devices with Robot related names

Sensei X Robotic Catheter System

• Pro Code – DXX system, catheter control, steerable
• Description – Steerable catheter control system (870.1290)
• Review Panel – Cardiovascular
• Device Class – II
• GMP Exempt – No

www.hansenmedical.com
Listed Devices with Robot related names

Remote Presence Robotic Systems

- Pro Code – DRG transmitters and receivers, physiological signal, radiofrequency
- Description – Radiofrequency physiological signal transmitter and receiver (870.2910)
- Review Panel – Cardiovascular
- Device Class – II
- GMP Exempt – No

www.intouchhealth.com
Listed Devices with Robot related names

Armeo Robotic arm exoskeleton

Lokomat robotic gait orthosis

- Pro Code – IKK system, isokinetic testing and evaluation
- Description – Isokinetic testing and evaluation system (890.1925)
- Review Panel – Physical Medicine
- Device Class – II, exempt
- GMP Exempt – No

www.hocoma.com
Listed Devices with Robot related names

Myomo e100 NeuroRobotic System Stroke Rehab Arm Brace

- Pro Code – OAL exercise equipment, powered, emg-triggered
- Description – Diagnostic electromyograph (890.1375)
- Review Panel – Physical Medicine
- Device Class – II
- GMP Exempt – No
- Technical method – EMG in affected area is sensed, processed, and used as an input to control a DC motor or other actuator that applies a force/torque to move an affected joint through range of motion.

www.myomo.com
Listed Devices with Robot related names

Robo-wrist

- Pro Code – ISZ unit, wrist, external limb component, mechanical
- Description – External limb prosthetic component (890.3420)
- Review Panel – Physical Medicine
- Device Class – I
- GMP Exempt – Yes

www.medicalbionics.com
Listed Devices with Robot related names

Noncon Robo Series Specular Microscope

- Pro Code – NQE microscope, specular
- Description – AC-powered slitlamp biomicroscope (886.1850)
- Review Panel – Ophthalmic
- Device Class – II
- GMP Exempt – No
Listed Devices with Robot related names

Robobact modular system for bacteriological screening

- Pro Code – JTW system, transport, aerobic
- Description – Microbiological specimen collection and transport device (866.2900)
- Review Panel – Microbiology
- Device Class – I
- GMP Exempt – No

www.ilexmedical.com
Premarket Review of Medical Robots

- A medical robot is:
  - not an intended use
  - not an indication for use
  - a technological characteristic
  - could affect risk to patient
- Robotic technology may affect:
  - device class
  - substantial equivalence determination

NATURE  16 May 2012
Mind-controlled robot arms show promise

Using a robot arm, 'Cathy' was able to lift a bottle for the first time in 15 years.

www.nature.com
Future Needs

• Innovative and emerging technologies are driving the regulatory process to become more flexible.

• Availability of guidances and recognized standards for new technologies can help industry provide FDA with the necessary information to determine device safety and effectiveness.