IOM ISSUES

- What is the current FDA Review Process?
- What standards are required to be met for FDA 510(k) clearance?
Topics

- Regulatory Review Process
  - Definitions
  - Device Classification
  - Performance Requirements
  - Labeling Requirements

- Use of Recognized Consensus Standards
Medical devices are “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or animals”
PREMARKET NOTIFICATION 510(K)

A marketing application submitted to FDA to demonstrate that the subject device is as safe and as effective (substantially equivalent) to an existing legally marketed (predicate) device.
510(k) Premarket Notification Submission

- Identification and Description of the Device
- Identification of and Comparison to a Legally Marketed Predicate Device
- Statement of Indications for Use
- Risk Analysis/ Mitigation Demonstrated by Performance Testing
- Labeling Review
Classification of Medical Gloves

- Surgeon’s Gloves – Class I
  (21 CFR 878.4460)
- Examination Gloves – Class I
  (21 CFR 880.6250)
- Premarket Notification [510(k)] is required prior to marketing ALL medical gloves in U.S.
Patient Examination Gloves
21 CFR 880.6250

“A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.”

- Primarily Non-Sterile
- Single-Use/Disposable
- Barrier Protection
  Protects wearer from blood-and fluid-borne pathogens
Surgeon’s Glove
21 CFR 878.4460

- "A surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination."

- Sterile

- Single-Use/Disposable

- Barrier Protection
  Protects patient from transmission of microorganisms and cross-infection
Three Regulatory Classes of Medical Devices

- **Class I**: Low risk - **General Control** - 510(k) exempt (mostly)
- **Class II**: Intermediate risk - Special & General Control - 510(k)
- **Class III**: High risk - Premarket Approval (PMA)
FDA Regulation of Medical Devices
General Controls

- Premarket Notification Submission [510(k)]
- Establishment Registration
- Medical Device Listing
- Good Manufacturing Practices
  - Quality System Regulation (QSR)
- Labeling Requirements
- Medical Device Reporting of Adverse Events
FDA Regulation of Medical Devices
Special Controls

- FDA Guidance Documents
- Regulatory Performance Standards
- Special Labeling Requirements
- Special User Education and Training
- Patient Registries
- Postmarket Surveillance

*Medical gloves are not subject to special controls.
Medical Glove Guidance Document

- FDA recommends that medical gloves cleared for marketing meet the minimum performance specifications described in the Guidance for Industry and FDA Staff - Medical Glove Guidance Manual issued January 22, 2008
- This document may be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073111.htm
Recognized Consensus Standards and FDA Guidance documents facilitate the premarket review process.

Conformance with Recognized Consensus Standards can provide reasonable assurance of safety and effectiveness for many aspects of medical device evaluation.

Standards produce voluntary consensus among industry, health care device users and FDA.

Standards are updated as technology and experience advance.
Medical Gloves
Material Composition

- Natural Rubber Latex
- Guayule
- Synthetic Polymers
  - Vinyl
  - Polychloroprene
  - Polyurethane
  - Isoprene
  - Nitrile
  - Neoprene/ styrene/ styrene-butadiene
- Chemical Additives
Use of Consensus Standards - Testing of Medical Gloves

- Latex Gloves   ASTM D 3578:2005
- Vinyl Gloves   ASTM D 5250:2006
- Synthetic Polymer Gloves   ASTM D 6977:2004
  \hspace{1cm} ASTM D 3578:2005
- Nitrile Gloves   ASTM D 6319:2005
- Surgeons’ Gloves   ASTM D 3577:2006
510(k) Review Process for Medical Gloves
Performance Requirements

- **Glove Specifications**
  - Water Leak Test (Pinhole AQL)
  - Physical Properties - Tensile Strength/ Elongation
  - Physical Dimensions
    - Length, width, thickness
  - Powder Free Residue
  - Protein Content (gloves made of natural rubber latex)
  - Powder Amount
510(k) Review Process for Medical Gloves
Performance Requirements

- Biocompatibility
  - Skin Irritation
  - Dermal Sensitization

- Sterilization Method and Validation (as appropriate)
  - Gloves should be tested to ensure that they meet the respective listed glove specifications AFTER sterilization
Use of Consensus Standards - Testing of Medical Gloves

- Detection of Holes

- Biocompatibility

- Resistance to Permeation-Chemotherapy Drugs
  - ASTM D 6978:2005
Use of Consensus Standards - Testing of Medical Gloves

STERILIZATION

- ANSI/AAMI/ISO 11135- Medical devices - Validation and routine control of ethylene oxide sterilization
- AAMI/CDV 11137 Sterilization of health care products – Radiation
510(k) Review Process for Medical Gloves Labeling

- Directions For Use
  - Satisfy requirements of 21 CFR 807.87(e) and 21 CFR part 801
  - Single Use/Disposable

- All medical gloves containing natural rubber latex must be labeled in bold print as required by 21 CFR 800.43(d)
  - “Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions”
Use of Consensus Standards Labeling

Attribute Labeling

- Powder-Free  2mg or less of residual powder
  - ASTM D 6124:2001
- Reduced Protein Level  50ugm/ dm² or less of extractable protein
  - ASTM D 5712:2005e1 (Lowry Test)
  - ASTM D 6499:2003  Measurement of Antigenic Protein
- Expiration Dating for Medical Gloves
  - ASTM D 7160-05
FDA Postmarket Activities

Surveillance

- The Medical Device Reporting regulation is a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical devices.
  - Medical Device Reporting (MDR)
  - MedWatch 1-800-FDA-1088
  - Safety Alerts & Public Health Advisories
  - Medical Bulletins
FDA Post Market Activities Compliance

- Factory Inspections
- FDA Sampling and Testing
- Detention
- Regulatory Sanctions
  - Adulteration
  - Misbranding
- Recalls and Safety Alerts
FDA/CDRH Responsibilities for Regulation of Medical Gloves

- Evaluate and **clear** medical gloves for marketing to ensure they are **safe** and **effective**
- **Inspect** manufacturing facilities to ensure the quality of devices
- **Surveillance and Compliance**
- Take **corrective actions** to remove devices from commercial distribution when they are unsafe, misbranded, or adulterated
- **Promote development** and use of standards
- **Communicate** and **educate** consumers
Where Can I Find Out More?

- General information:  
  http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/PersonalProtectiveEquipment/ucm056084.htm
  http://www.fda.gov/MedicalDevices/Safety/default.htm

- For copies of slides:  
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Thank You

Questions/ Comments?