CLIA - Unregulated Clinical Tests

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January 30, 2002

Monitoring Respiratory Devices

(reviewed by DCRD)

- Pulmonary Function Tests
- Cardiovascular Monitors
- Pulse oximeters
- Indwelling arterial sensors

Diagnostic Respiratory Devices

(reviewed by DCLD)

- Measurement of exogenous production of gases (e.g., nitric oxide)
- Exhaled breath analysis (variety of analytes)

Premarket notification

- Required to have a cleared premarket notification - 510(k)
- 510(k) must show that the device is substantially equivalent to predicate devices
- Performance testing required by DCRD to demonstrate substantial equivalence

Pulmonary Function Tests

- Spirometry
- Static Lung Volumes
  - Indications for use are functional (e.g., measure volumes and flows)
  - Do not provide a diagnosis

Pulmonary Function Tests

- Performance testing
  - Demonstrate that the accuracy of the device is comparable to that of predicate devices
  - American Thoracic Society Standards
    - Standards includes test methods and performance requirements for a variety of devices
    - e.g., volume accuracy for spirometers is $\pm$3% over a 7 L volume range; bench testing done with a database of waveforms, and human subjects

General Standards

- Biocompatability Testing
  - ISO 10993
- Electrical and Mechanical Safety
  - IEC 60601-1
- Electromagnetic Compatibility
  - IEC 60101-1-2; CISPR 11

Pulmonary Function Tests

- Labeling is reviewed to ensure it includes:
  - instructions for use
  - tested accuracy of the device
  - validated instructions for calibrating the device

Cardiovascular Monitoring

- Principle types of CV monitoring devices:
  - *ECG and heart rate*
  - *Non-invasive blood pressure*
  - Intracardiac catheters to measure pressure, volume and temperature
  - Pulse oximetry (estimation of arterial oxygen saturation)
  - Indwelling arterial sensors (e.g., pH, pO_2, pCO_2)

Intracardiac catheters

- May be inserted through Swan-Ganz catheters
- Intracardiac temperature measurements used to estimate cardiac output using the thermodilution method
- Intracardiac pressure and/or volume
- Blood sampling
- Measure physiological parameters; do not make a diagnosis

Intracardiac catheters

- Performance
  - Bench testing to show equivalent performance at a functional level
  - Animal or clinical testing required to demonstrate performance under actual conditions of use if design is different from predicate

Intracardiac catheters

- Review issues
  - Mechanical and electrical integrity under expected conditions of use - bench and animal testing
  - Biocompatability
  - Sterility and package integrity

Pulse Oximetry

- Non-invasive, real-time method to **estimate** arterial oxygen saturation and/or heart rate
- Probe placed on the fingertip or earlobe
- Method is based of the differential absorption of oxy-hemoglobin to light at different wavelength
- Requires pulsatile flow to function properly

Pulse Oximetry

- Performance testing - desaturation study
  - Human validation study to demonstrate device accuracy
  - Device performance compared to an co-oximeter
  - Eight volunteers provide oxygen saturation data over the range of 70-100% (200 datapoints)
  - Accuracy must be within $\pm$ 3%
  - Labeling includes accuracy results

Pulse Oximeter

- Biocompatability Testing
  - ISO 10993
- Electrical and Mechanical Safety
  - IEC 60601-1
- Electromagnetic Compatibility
  - IEC 60101-1-2; CISPR 11

Indwelling Arterial Sensor

- Indicated to provide continuous reading of arterial pH and partial pressure of gases such as oxygen, carbon dioxide, and oxyhemoglobin

Indwelling Arterial Sensor

- Performance testing
  - Clinical testing required to demonstrate performance under actual conditions of use if design is different from predicate
  - Bench and/or animal testing to show mechanical and electrical integrity under expected conditions of use
  - NCCLS standards

Indwelling Arterial Sensor

- Biocompatability Testing
  - ISO 10993
- Electrical and Mechanical Safety
  - IEC 60601-1
- Electromagnetic Compatibility
  - IEC 60101-1-2; CISPR 11
- Sterilization and Pyrogenicity

Hemodialysis Monitor

- Inline sensors to monitor arterial oxygen saturation and hematocrit
- Values are used to provide an ESTIMATE of blood volume
- Clinical data required to validate device performance

Conclusion

- The devices presented are used to monitor a variety of physiological parameters
- Under the 510(k) program, firms are required to conduct performance testing to validate device design
- Quality System Regulation requirements ensure quality of the finished device