Legal
Legal framework: Yes
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Center for Devices and Radiological Health (CDRH), Food and Drugs Administration (FDA) www.fda.gov
Responsibilities of the NRA: The CDRH is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States. In addition, CDRH regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm

Medical device definition
Medical device defined: Yes
Text: A medical device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--
(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
(2) 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
(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve 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 its primary intended purposes.
In vitro diagnostic medical device (IVD) defined: Yes
Text: Included under the definition of “medical devices” under law, but defined separately in regulation.
21 CFR 809.3.

Medical device classification
Classification: Yes
Categories: Class I, II, and III.
Classification rules: Yes
Classification rules details: Classification broadly depends on the intended use as well as the indications for use. Most products may be classified by finding a matching description of the device in 21 C.F.R. Parts 862-92. See also http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm

Essential principles
Essential principles: Yes
Details: N/A

Conformity assessment
Conformity assessment bodies: Yes
Details: Yes - The Center for Devices and Radiological Health (CDRH) has a Third Party Review Program that provides manufacturers of certain devices of submitting a 510(k) application to a private party rather than directly to the FDA.
Pre-marketing / procedure: Yes - Depending on the classification of a medical device, one must either obtain a Premarket Approval or establish “substantial equivalence” to a legally marketed device (i.e. Premarket Notification 510(k) application). 21 C.F.R. 807.92(a)(3). Generally, most Class I devices are exempt from the Premarket Notification 510(k), unlike Class II and III devices. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm

Reliance
Reliance: No
Details: The FDA does not recognize regulatory approvals from other countries. http://www.fda.gov/medicaldevices/deviceregulationandguidance/importingandexportingdevices/ucm050126.htm
Jurisdictions: N/A
WHO Region of the Americas

Clinical investigation
Clinical investigation controls: Yes
Details: Only clinical studies of devices that pose significant risk must be approved by the FDA and by an Institutional Review Board (IRB) before the study may commence. (Studies with devices that pose a nonsignificant risk must be approved by just the IRB.) http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm#ide

Registration and listing
Registration of establishment: Yes
Details: Manufacturers (domestic and foreign) and importers of medical devices must register their establishments with the FDA.
See generally 21 C.F.R. Part 807.
Listing of medical devices: Yes
Details: Manufacturers must list their devices with the FDA.

Import controls
Import controls: Yes
Details: Foreign manufacturers of medical devices must comply with US regulations before, during, and after they import medical devices into the US. Foreign manufacturers must meet requirements such as establishment registration, listing devices, QMS, adverse event reporting, and Premarket Approval or Premarket Notification 510(k). Initial importers must register their establishment with the FDA, and they are subject to Medical Device Reporting. All imported medical devices must also meet customs requirements. http://www.fda.gov/medicaldevices/deviceregulationandguidance/importingandexportingdevices/ucm050126.htm

Post market controls
Post Market Surveillance: Yes
Details: The CDRH has several mechanisms to conduct post-market surveillance. Those include:
- Medical Device Reporting (MDR) - reports of confirmed or possible device-associated serious injuries, deaths, or malfunctions
- Medical Product Safety Network (MedSun) - enhanced surveillance network of 280 hospitals nationwide
- Post-Approval Studies - used to assess device safety, effectiveness, and/or reliability
- Postmarket Surveillance Study - the FDA may order a manufacturer of certain Class II and III devices to conduct postmarket surveillance studies (i.e. “522 studies”), and it maintains a list of those studies.
- FDA Discretionary Studies - FDA conducts its own studies to assess device performance and clinical outcomes, investigate adverse events, and characterize device-associated benefits/risks for patients.
http://www.fda.gov/MedicalDevices/Safety/CDRHPostmarketSurveillance/ucm348738.htm

Inspection (QMS): Yes
Details: A comprehensive inspection is required to be done when performing a compliance inspection (OAI follow-up inspection) of a firm. It must include all of the items discussed under Directed Device Inspections http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm114955.htm#COMPREHENSIVE

Enforcement: Yes
Details: The FDA has authority to take both administrative (FDA devises and then takes action) and judicial actions (federal court decides and then takes action at the request of the Department of Justice and FDA). The FDA can carry out inspections and criminal investigations. http://www.fda.gov/aboutfda/transparency/transparencyinitiative/ucm254426.htm
In rare instances, the FDA may issue a recall order where the manufacturer or importer fails to do so.
21 CFR 810; FD&C § 518D.

Adverse event reporting: Yes
Details: Manufacturers, importers, and device user facilities must report certain device-related adverse events and problems to the FDA. 21 CFR 803.

Field safety corrective action monitoring: Yes
Details: A recalling firm must develop a recall strategy, and the FDA will review the adequacy of the proposed strategy and recommend changes as appropriate. http://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/recallscorrectionsandremovals/default.htm

Advertising: Yes
Details: Almost all advertisement is considered labelling pursuant to an appellate court decision. Accordingly, the same labelling rules apply to advertisements. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabelling/default.htm

Labelling: Yes
Details: The FDA administers regulations for medical devices. Requirements vary, based on the type of device. E.g., 21 CFR Part 801 (general device labelling); 21 CFR Part 809 (IVDs).

Limitations: these data reflect a limited view and do not capture what may currently occur within Member States or how they implemented the data. Complete verification of the data may not be immediately possible and inaccuracies may linger. Mis-categorization or non-capture of a country’s regulatory framework is possible due to translation and interpretation.