U.S. FOOD & DRUG ADMINISTRATION

FDA FACT SHEET

MEDICAL DEVICE INSPECTION CONTRACT PROGRAM

Program Description

- The purpose of the Medical Device Contract Program is to obtain state assistance in the inspection of Class I and Class II medical device manufacturers.
- FDA classifies devices as the following:
  - Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. For example, dental floss is classified as Class I device.
  - Class II devices are higher risk devices and therefore require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness.

Intended Outcomes

- Determine compliance with the FDA's Guide to Inspections of Quality Systems (QSIT) and Good Manufacturing Practice (GMP) regulations.
- Determine whether management with executive responsibility ensures an adequate and effective quality system has been established (defined, documented, and implemented at the firm).
- Increase the protection of public health and improve consumer confidence in the device industry. By entering into medical device contracts, district workload can be converted from an inspectional role to a minority role.

Program Metrics

- Contracted inspections under program: 80
- Current number of awards: 2
- Current partners: Texas, California

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.

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