Screen: Introduction

CDRH Allegation Reporting (Medical Devices)

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This software application is intended to provide an electronic means for reporting voluntary allegations regarding medical devices to the Center for Devices and Radiological Health (CDRH). An allegation is a notification that a product in commercial distribution may be in violation of the laws and regulations administrated by the FDA.

Voluntary Complaints of Allegations of Regulatory Violations may pertain to the following subject matters:

- Promotion and advertisting issues
- Failure to report issues and/or follow-up investigations regarding Medical Device Reporting (MDR)
- Quality Systems/Good Manufacturing Practices (GMP) issues
- Unapproved or not cleared device issues
- Import Issues
- Export Issues
- Trade Industry (e.g. trade group, professionals, industry, etc.) issues
- Registration and Listing issues
- Counterfeit issues
- Health Fraud issues
- Criminal issues involving a product