

Download Medical Devices Protecting Patients And Promoting Innovation

Pediatric medical devices treat or diagnose diseases and conditions from birth through age 21. The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines pediatric patients as persons aged 21 or ...FDA Responsibility for Medical Devices • FDA regulates medical devices, including: – simple items like tongue depressors and bedpans – complex technologies such as heart pacemakersThe FDA impacts our lives every day – from the food we eat and drugs we take, to the medical devices and products we use. More than 20 percent of the goods in the U.S. economy are under our ...As described in Chapter 3, FDA has authority for two programs of adverse event reporting that involve medical devices. The primary program receives mandatory reports of certain adverse device events from device manufacturers and user facilities and also accepts voluntary reports from health care professionals, consumers, and others.