



## Pediatric Medical Devices: Provisions Support Development, But Better Data Needed for Required Reporting: Gao-12-225

By -

BiblioGov. Paperback. Book Condition: New. This item is printed on demand. Paperback. 60 pages. Dimensions: 9.7in. x 7.4in. x 0.1in. Certain characteristics unique to pediatric populations-including physiological differences from adult patients and challenges with recruiting pediatric participants for clinical trials-are barriers to developing medical devices for pediatric use cited by stakeholders. Given the unique characteristics of the pediatric population, and because the market for pediatric devices is smaller than the market for adult devices, there are limited economic incentives for manufacturers to develop pediatric medical devices. FDAAA provisions authorized demonstration grants for pediatric device consortia-these consortia reported assisting over 100 pediatric device projects in the first 2 years of the program, fiscal years 2009 and 2010. FDA awarded grants totaling about 5 million to four pediatric device consortia in these 2 years. Of the device projects assisted by the consortia, many projects were in early stages of development, such as the creation of a prototype and the preclinical testing of that prototype. Activities performed by the consortia included regularly scheduled forums where innovators could discuss new device ideas with a group of experts. This item ships from La Vergne, TN. Paperback.



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