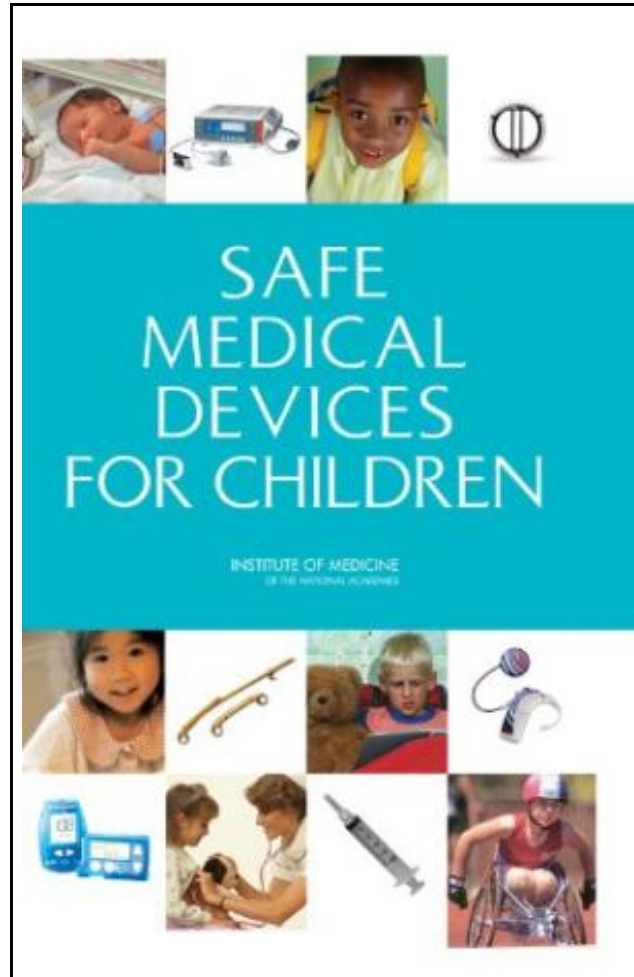


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National Academies Press, United States, 2006. Hardback. Book Condition: New. 231 x 155 mm. Language: English . Brand New Book. Innovative medical devices have helped reduce the burden of illness and injury and improve the quality of life for countless children. Mechanical ventilators and other respiratory support devices rescue thousands of fragile newborns every year. Children who once would have died of congenital heart conditions survive with the aid of implanted pacemakers, mechanical heart valves, and devices that close holes in the heart. Responding to a Congressional request, the Institute of Medicine assesses the system for postmarket surveillance of medical devices used with children. The book specifically examines: * The Food and Drug Administration's (FDA's) monitoring and use of adverse event reports * The agency's monitoring of manufacturers' (FDA's) fulfillment of commitments for postmarket studies ordered at the time of a device's (FDA's) approval for marketing * The adequacy of postmarket studies of implanted devices to evaluate the effects of children's (FDA's) active lifestyles and their growth and development on device performance Postmarket surveillance of medical devices used with children is a little investigated topic, in part because the market for most medical products is concentrated among older adults. Yet children differ from adults, and their special characteristics have implications for evaluation and monitoring of the short- and long-term safety and effectiveness of medical devices used with young patients.



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