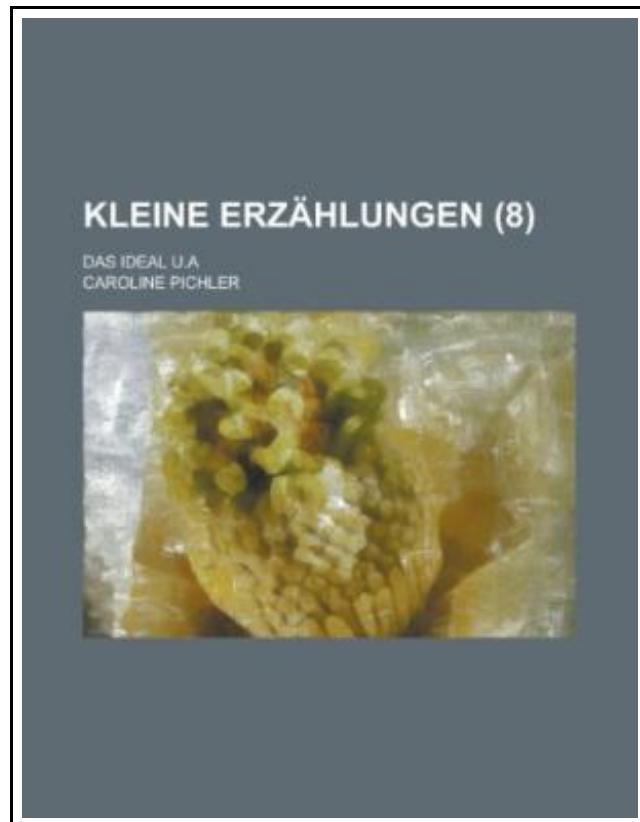


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RareBooksClub. Paperback. Book Condition: New. This item is printed on demand. Paperback. 32 pages. Original publisher: Washington, D. C. : U. S. Govt. Accountability Office, 2007 OCLC Number: (OCO)182761572 Subject: Artificial temporomandibular joints. Excerpt: . . . Table 1: GAO Categorization of Concerns Raised by FDA during the PMA Process for TMJ Implants Categories of concerns Types of concerns included in categories Inadequate or inaccurate clinical study results, including: Study protocol Inaccurate measurement of data (e. g. , problems with procedures used to measure pain over a time) a Data not separated appropriately (e. g. , results from different implants analyzed together) a Questionable conduct by sponsor (e. g. , underreporting of adverse events) a Incomplete or insufficient data to draw conclusions a Lack of long-term data collection a Unsupported or poorly defined indications for use Lack of patient history data, including: a Patients clinical diagnosis unknown (e. g. , rheumatoid arthritis, cancer) Patients treatment history unknown (e. g. , first implant, multiple implants) Original sample size of study too small b Lack of patient follow-up, including: Patient follow-up a Long-term data lacking due to poor follow-up a Number of patients in study too small due to poor follow-up Inadequate wear testing, including: Engineering testing a Analysis of wear debris from implant lacking a No examination for wear of implants removed from patients a, c No analysis of wear on natural condyle a, d Inadequate fatigue testing a Other engineering testing inadequate a Inadequate device labeling Other e Unaddressed microbiology, packaging, and shelf-life issues Incomplete sponsor manufacturing inspections Source: GAO analysis of FDA documents. Notes: This table applies to the four TMJ implants approved since December 30, 1998. a These concerns were also raised by the dental products panel in...

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