FDA 510(k) Premarket Notification

K011997 MODULAR VALVE HANDLES FOR ADAPTABLE TUBES, MODEL 1298-XX-XX, 1295-XX-XX

CLEARED

Jul 10, 2001
13 days to decision

K011997 · Product code: **GCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k011997/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jun 27, 2001
Decision date	Jul 10, 2001
Days to decision	13 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Pajunk GmbH**
Location	Washington, DC, US
Contact	MARTIN HAUGER
510(k) history	19 submissions · 19 cleared · 1991-2012

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k011997/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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