FDA 510(k) Premarket Notification

K073096 ANCHORAGE CLOSURE DEVICE

CLEARED

Feb 7, 2008
98 days to decision

K073096 · Product code: **GAT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k073096/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Nov 1, 2007
Decision date	Feb 7, 2008
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Epitek, Inc.**
Location	Bloomington, MN, US
Contact	WERNER HAMPL
510(k) history	3 submissions · 3 cleared · 2008-2008

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k073096/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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