FDA 510(k) Premarket Notification

CLEARED

K060878 GELITA-SPON ABSORBABLE GELATIN SPONGE, USP

Apr 13, 2006
13 days to decision

K060878 · Product code: **KHJ** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k060878/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Polymer, Ent Synthetic-polyamide (mesh Or Foil Material) (KHJ)
Date received	Mar 31, 2006
Decision date	Apr 13, 2006
Days to decision	13 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Curamedical, BV**
Location	Claremont, NH, US
Contact	WILLIAM GREENROSE
510(k) history	2 submissions · 2 cleared · 2005-2006

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k060878/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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