FDA 510(k) Premarket Notification

K030081 CSF400 AND CSF600

CLEARED

Oct 6, 2003
270 days to decision

K030081 · Product code: **JXG** · Neurology
Source: https://www.510kdatabase.net/k030081/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Jan 9, 2003
Decision date	Oct 6, 2003
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Inmed Ltda.**
Location	Alpharetta, GA, US
Contact	JAY MANSOUR
510(k) history	3 submissions · 3 cleared · 2003-2003

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k030081/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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