FDA 510(k) Premarket Notification

K100800 TIDI FACEMASK

CLEARED

Jun 14, 2010
84 days to decision

K100800 · Product code: **FXX** · General Hospital
Source: https://www.510kdatabase.net/k100800/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Mar 22, 2010
Decision date	Jun 14, 2010
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tidi Products,Llc**
Location	Neenah, WI, US
Contact	DION BRANDT
510(k) history	3 submissions · 3 cleared · 2010-2014