FDA 510(k) Premarket Notification

K121272 PROTECH DENT

CLEARED

Oct 15, 2012
171 days to decision

K121272 · Product code: **OBR** · Dental
Source: https://www.510kdatabase.net/k121272/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	Apr 27, 2012
Decision date	Oct 15, 2012
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Akervall Technologies, Inc.**
Location	Ann Arbor, MI, US
Contact	SASSA AKERVALL
510(k) history	1 submissions · 1 cleared · 2012-2012