FDA 510(k) Premarket Notification

K042517 BIOSORB FX AND BIOSORB PDX 1.5 AND 2.0 SCREWS

CLEARED

Oct 8, 2004
23 days to decision

K042517 · Product code: **JEY** · Dental
Source: https://www.510kdatabase.net/k042517/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Bone (JEY)
Date received	Sep 15, 2004
Decision date	Oct 8, 2004
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Linvatec Biomaterials, Ltd.**
Location	Largo, FL, US
Contact	TUIJA ANNALA
510(k) history	5 submissions · 5 cleared · 2003-2004