FDA 510(k) Premarket Notification

K023819 FIBERFILL SGP

CLEARED

Mar 26, 2003
131 days to decision

K023819 · Product code: **EKM** · Dental
Source: https://www.510kdatabase.net/k023819/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gutta-percha (EKM)
Date received	Nov 15, 2002
Decision date	Mar 26, 2003
Days to decision	131 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Pentron Clinical Technologies**
Location	Wallingford, CT, US
Contact	ANNMARIE TENERO
510(k) history	13 submissions · 13 cleared · 2002-2009