FDA 510(k) Premarket Notification

K915653 KERAMAIL

CLEARED

Apr 8, 1993
477 days to decision

K915653 · Product code: **EIH** · Dental
Source: https://www.510kdatabase.net/k915653/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Dec 18, 1991
Decision date	Apr 8, 1993
Days to decision	477 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Wilde-USA, Inc.**
Location	Naperville, IL, US
Contact	ROBERT BAUER
510(k) history	16 submissions · 16 cleared · 1991-1993