FDA 510(k) Premarket Notification

K896361 HANDPIECE FIBER OPTIC SYSTEM IMPROVEMENT FEATURE

CLEARED

Feb 2, 1990
88 days to decision

K896361 · Product code: **EFB** · Dental
Source: https://www.510kdatabase.net/k896361/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Nov 6, 1989
Decision date	Feb 2, 1990
Days to decision	88 days
Third-party review	No

APPLICANT

Company	**Dentalez Group**
Location	Lancaster, PA, US
Contact	DONALD I GONSER
510(k) history	13 submissions · 13 cleared · 1988-2003

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k896361/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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