

K912997 MINIFLEX AND PERSONAL UNITOct 30, 1991
114 days to decisionK912997 · Product code: **EAZ** · Dental
Source: <https://www.510kdatabase.net/k912997/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Operating, Dental (EAZ)
Date received	Jul 8, 1991
Decision date	Oct 30, 1991
Days to decision	114 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Dabi-Atlante America Corp.
Location	Tampa, FL, US
Contact	R FERNANDES
510(k) history	4 submissions · 4 cleared · 1991-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k912997/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 3, 2026