

K854347 HYBRID POINTSDec 27, 1985
59 days to decisionK854347 · Product code: **DZP** · DentalSource: <https://www.510kdatabase.net/k854347/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Diamond, Dental (DZP)
Date received	Oct 29, 1985
Decision date	Dec 27, 1985
Days to decision	59 days
Third-party review	No

APPLICANT

Company	Shofu Dental Corp.
Location	Mchenry, IL, US
Contact	MARTY DYMEK
510(k) history	59 submissions · 59 cleared · 1981-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k854347/>; 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 June 16, 2026