

**K945398 BRANEMARK SYSTEM(R) MKII SELF-TAPPING
FIXTURE**Apr 13, 1995
161 days to decisionK945398 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k945398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Nov 3, 1994
Decision date	Apr 13, 1995
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nobelpharma USA, Inc.
Location	Chicago, IL, US
Contact	MARY EDWARDS
510(k) history	64 submissions · 64 cleared · 1990-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k945398/> 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