

**K981362 SYNTHES (USA) EXTERNAL MULTI VECTOR
MANDIBLE DISTRACTOR**Jun 29, 1998
75 days to decisionK981362 · Product code: **DZL** · Dental
Source: <https://www.510kdatabase.net/k981362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Intraosseous (DZL)
Date received	Apr 15, 1998
Decision date	Jun 29, 1998
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes (Usa)
Location	Mchenry, IL, US
Contact	SHERI L MUSGNUNG
510(k) history	411 submissions · 394 cleared · 1977-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981362/> 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 May 14, 2026