FDA 510(k) Premarket Notification

K981459 MEMBRANE TACK

CLEARED

Jul 14, 1998
82 days to decision

K981459 · Product code: **DZL** · Dental
Source: https://www.510kdatabase.net/k981459/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Intraosseous (DZL)
Date received	Apr 23, 1998
Decision date	Jul 14, 1998
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet, Inc.**
Location	Mchenry, IL, US
Contact	MARY VERSTYNEN
Website	http://www.biomet.com/
510(k) history	441 submissions · 419 cleared · 1978-2026

Biomet, Inc. is an orthopedic medical device manufacturer based in McHenry, US. The company specializes in surgical implants, fixation systems, and trauma solutions. Biomet has maintained a strong FDA 510(k) regulatory record since its first clearance in 1978. The company has received FDA 510(k) clearances from total submissions. Orthopedic devices represent 88% of its submission portfolio, reflecting the company's core focus on joint reconstruction, trauma fixation, and surgical instrumentation. The latest clearance in 2024 demonstrates continued regulatory activity and ...