FDA 510(k) Premarket Notification

K050635 ALLFIM IMPLANT SYSTEMS

CLEARED

Jul 28, 2005
119 days to decision

K050635 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k050635/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 31, 2005
Decision date	Jul 28, 2005
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cowellmedi Co., Ltd.**
Location	Newington, NH, US
Contact	DAE KYU CHANG
510(k) history	14 submissions · 14 cleared · 2004-2025