FDA 510(k) Premarket Notification

K820013 TITANIUM IMPLANT DEVICES

CLEARED

Mar 1, 1982
55 days to decision

K820013 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k820013/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jan 5, 1982
Decision date	Mar 1, 1982
Days to decision	55 days
Third-party review	No

APPLICANT

Company	**Bofors Nobelpharma, Inc.**
Location	Mchenry, IL, US
510(k) history	3 submissions · 3 cleared · 1982-1984