FDA 510(k) Premarket Notification

K842358 ISOLIGHT

CLEARED

Jul 31, 1984
39 days to decision

K842358 · Product code: **EBA** · Dental
Source: https://www.510kdatabase.net/k842358/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light, Surgical Headlight (EBA)
Date received	Jun 22, 1984
Decision date	Jul 31, 1984
Days to decision	39 days
Third-party review	No

APPLICANT

Company	**Planmeca USA, Inc.**
Location	Mchenry, IL, US
510(k) history	13 submissions · 13 cleared · 1984-2011