

**K842358 ISOLIGHT**Jul 31, 1984  
39 days to decisionK842358 · 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	<b>Planmeca USA, Inc.</b>
Location	Mchenry, IL, US
510(k) history	13 submissions · 13 cleared · 1984-2011

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k842358/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 17, 2026