

**K780528 PREMIER CARVERS, STYLE #21C & 21D**Apr 19, 1978  
16 days to decisionK780528 · Product code: **EKH** · Dental  
Source: <https://www.510kdatabase.net/k780528/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Carver, Dental Amalgam, Operative (EKH)
Date received	Apr 3, 1978
Decision date	Apr 19, 1978
Days to decision	16 days
Third-party review	No

**APPLICANT**

---

Company	<b>Premier Dental Products Co.</b>
Location	Mchenry, IL, US
510(k) history	41 submissions · 41 cleared · 1977-2014

---

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

Device record: <https://www.510kdatabase.net/k780528/> 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 June 13, 2026