

K896661 KEN'S PROPHY GEL - REGULARFeb 14, 1990
82 days to decisionK896661 · Product code: **EJR** · DentalSource: <https://www.510kdatabase.net/k896661/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Polishing, Abrasive, Oral Cavity (EJR)
Date received	Nov 24, 1989
Decision date	Feb 14, 1990
Days to decision	82 days
Third-party review	No

APPLICANT

Company	Puldent Corp.
Location	Watertown, MA, US
Contact	KENNETH J BERK
510(k) history	78 submissions · 78 cleared · 1990-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k896661/>, Data sourced from FDA 510(k) public records (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. - Generated July 2, 2026