FDA 510(k) Premarket Notification

K123215 VISCOSTAT CLEAR

CLEARED

Feb 5, 2013
113 days to decision

K123215 · Product code: **MVL** · Dental
Source: https://www.510kdatabase.net/k123215/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cord, Retraction (MVL)
Date received	Oct 15, 2012
Decision date	Feb 5, 2013
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ultradent Products, Inc.**
Location	Salt Lake City, UT, US
Contact	KAREN KAKUNES
Website	https://www.ultradent.com
510(k) history	103 submissions · 103 cleared · 1992-2026