FDA 510(k) Premarket Notification

K082043 CARRIAZO-PENDULAR MICROKERATOME

CLEARED

Aug 1, 2008
14 days to decision

K082043 · Product code: **HNO** · Ophthalmic
Source: https://www.510kdatabase.net/k082043/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Keratome, Ac-powered (HNO)
Date received	Jul 18, 2008
Decision date	Aug 1, 2008
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Schwind Eye-Tech-Solutions GmbH & Co. KG**
Location	Coto De Caza, CA, US
Contact	ROLF SCHWIND
510(k) history	2 submissions · 2 cleared · 2004-2008