K131787 CRYOMATIC MKII CONSOLE, CRYOMATIC MKII PROBES, DISPOSABLE CRYO PROBES

CLEARED

Dec 23, 2013
188 days to decision

K131787 · Product code: **HRN** · Ophthalmic
Source: https://www.510kdatabase.net/k131787/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Cryophthalmic, Ac-powered (HRN)
Date received	Jun 18, 2013
Decision date	Dec 23, 2013
Days to decision	188 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Keeler, Ltd.**
Location	Broomall, PA, US
Contact	EUGENE R VANARSDALE
Website	http://www.keeler.co.uk/
510(k) history	4 submissions · 4 cleared · 2010-2014