FDA 510(k) Premarket Notification

K093473 KMD-MARK1 TISSUE MARKER

CLEARED

Jul 2, 2010
238 days to decision

K093473 · Product code: **NEU** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k093473/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Nov 6, 2009
Decision date	Jul 2, 2010
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kent Medical Devices, Inc.**
Location	Washington, DC, US
Contact	JUSTIN EGGLETON
510(k) history	1 submissions · 1 cleared · 2010-2010