FDA 510(k) Premarket Notification

K031938 GEL MARK III BIOPSY SITE MARKER

CLEARED

Sep 5, 2003
74 days to decision

K031938 · Product code: **NEU** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k031938/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Jun 23, 2003
Decision date	Sep 5, 2003
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Senorx, Inc.**
Location	Irvine, CA, US
Contact	AMY BOUCLY
510(k) history	30 submissions · 26 cleared · 2000-2023