FDA 510(k) Premarket Notification

K882013 SOFT TISSUE BIOPSY DEVICE

CLEARED

Jun 15, 1988
33 days to decision

K882013 · Product code: **DWO** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k882013/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Biopsy, Cardiovascular (DWO)
Date received	May 13, 1988
Decision date	Jun 15, 1988
Days to decision	33 days
Third-party review	No

APPLICANT

Company	**Ocean Medical Products, Ltd.**
Location	Mchenry, IL, US
Contact	ALAN TAYLOR
510(k) history	9 submissions · 9 cleared · 1981-1988