FDA 510(k) Premarket Notification

K885149 NEEDLE INSERT FOR SOFT TISSUE BIOPSY DEVICE

CLEARED

Jan 26, 1989
42 days to decision

K885149 · Product code: **DWO** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k885149/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Biopsy, Cardiovascular (DWO)
Date received	Dec 15, 1988
Decision date	Jan 26, 1989
Days to decision	42 days
Third-party review	No

APPLICANT

Company	**Hart Enterprises, Inc.**
Location	Wyoming, MI, US
Contact	ALAN TAYLOR
510(k) history	4 submissions · 4 cleared · 1988-1993