FDA 510(k) Premarket Notification

K913815 AUTOMATED BIOPSY DEVICE, MODIFICATION

CLEARED

Oct 30, 1991
65 days to decision

K913815 · Product code: **DWO** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k913815/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Biopsy, Cardiovascular (DWO)
Date received	Aug 26, 1991
Decision date	Oct 30, 1991
Days to decision	65 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k913815/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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