

K101960 SONOTRAX SERIES ULTRASONIC POCKET DOPPLERAug 10, 2010
29 days to decisionK101960 · Product code: **HEP** · Radiology
Source: <https://www.510kdatabase.net/k101960/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Blood-flow, Ultrasonic (HEP)
Date received	Jul 12, 2010
Decision date	Aug 10, 2010
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Edan Instruments, Inc.
Location	Shenzhen, CN
Contact	YUE QIUHONG
Website	https://www.edan.com.cn
510(k) history	92 submissions · 92 cleared · 2004-2026

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