FDA 510(k) Premarket Notification

K801811 PALPATION ENHANCER

CLEARED

Sep 9, 1980
63 days to decision

K801811 · Product code: **LDE** · Cardiovascular
Source: https://www.510kdatabase.net/k801811/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Manual (LDE)
Date received	Jul 8, 1980
Decision date	Sep 9, 1980
Days to decision	63 days
Third-party review	No

APPLICANT

Company	**Medical Horizons Co.**
Location	Mchenry, IL, US
510(k) history	1 submissions · 1 cleared · 1980-1980