FDA 510(k) Premarket Notification

K890080 PHACOEMULSIFIER MODEL 100

CLEARED

Apr 6, 1989
87 days to decision

K890080 · Product code: **HQC** · Ophthalmic
Source: https://www.510kdatabase.net/k890080/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Phacofragmentation (HQC)
Date received	Jan 9, 1989
Decision date	Apr 6, 1989
Days to decision	87 days
Third-party review	No

APPLICANT

Company	**Sonic Needle Corp.**
Location	Farmingdale, NY, US
Contact	RALPH WERTHEIMER
510(k) history	1 submissions · 1 cleared · 1989-1989