FDA 510(k) Premarket Notification

K884076 SUREBREATH DOME

CLEARED

Oct 7, 1988
10 days to decision

K884076 · Product code: **GAD** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k884076/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Retractor (GAD)
Date received	Sep 27, 1988
Decision date	Oct 7, 1988
Days to decision	10 days
Third-party review	No

APPLICANT

Company	**Ipax, Inc.**
Location	CO, US
Contact	PENNELL
510(k) history	18 submissions · 18 cleared · 1984-2021