FDA 510(k) Premarket Notification

K800839 MEDESCAN

CLEARED

May 30, 1980
45 days to decision

K800839 · Product code: **KTA** · Radiology
Source: https://www.510kdatabase.net/k800839/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medium, Contrast, Radiologic (KTA)
Date received	Apr 15, 1980
Decision date	May 30, 1980
Days to decision	45 days
Third-party review	No

APPLICANT

Company	**Medefield Pty. , Ltd.**
Location	Mchenry, IL, US
510(k) history	6 submissions · 6 cleared · 1980-1980