FDA 510(k) Premarket Notification

K862616 AMBER-CHEST

CLEARED

Sep 2, 1986
55 days to decision

K862616 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k862616/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Jul 9, 1986
Decision date	Sep 2, 1986
Days to decision	55 days
Third-party review	No

APPLICANT

Company	**Old Delft Corp. of America**
Location	Fairfax, VA, US
Contact	DE BRUIN
510(k) history	3 submissions · 3 cleared · 1986-1986