FDA 510(k) Premarket Notification

K922813 GEN-X 800-400 -- MODIFICATION

CLEARED

Aug 11, 1992
81 days to decision

K922813 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k922813/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	May 22, 1992
Decision date	Aug 11, 1992
Days to decision	81 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Swiss Ray Medical Systems**
Location	Mobile, AL, US
Contact	MICHAEL W SCOTT
510(k) history	3 submissions · 3 cleared · 1992-1992