FDA 510(k) Premarket Notification

K790418 MODEL 8100 PRE-FILLED INTRAUTERINE

CLEARED

Mar 21, 1979
21 days to decision

K790418 · Product code: **KXO** · Radiology
Source: https://www.510kdatabase.net/k790418/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Pressure, Intrauterine (KXO)
Date received	Feb 28, 1979
Decision date	Mar 21, 1979
Days to decision	21 days
Third-party review	No

APPLICANT

Company	**Ge Medical Systems Information Technologies**
Location	Mchenry, IL, US
510(k) history	136 submissions · 132 cleared · 1978-2012