FDA 510(k) Premarket Notification

K800222 MODEL 412 ELECTROFLUIDIC MANOMETER

CLEARED

Feb 29, 1980
25 days to decision

K800222 · Product code: **DXW** · Cardiovascular
Source: https://www.510kdatabase.net/k800222/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Phonocatheter, Intracavitary (DXW)
Date received	Feb 4, 1980
Decision date	Feb 29, 1980
Days to decision	25 days
Third-party review	No

APPLICANT

Company	**Med-Tek Corp.**
Location	Mchenry, IL, US
510(k) history	16 submissions · 15 cleared · 1978-1990