FDA 510(k) Premarket Notification

K781641 SURGITEK DOUBLE J URETEROL STENT

CLEARED

Dec 7, 1978
77 days to decision

K781641 · Product code: **FAD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k781641/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Sep 21, 1978
Decision date	Dec 7, 1978
Days to decision	77 days
Third-party review	No

APPLICANT

Company	**Medical Engineering Corp.**
Location	Mchenry, IL, US
510(k) history	28 submissions · 28 cleared · 1977-1993