FDA 510(k) Premarket Notification

K802060 STERILE TONSIL SPONGES

CLEARED

Oct 10, 1980
46 days to decision

K802060 · Product code: **GDY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k802060/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal, X-ray Detectable (GDY)
Date received	Aug 25, 1980
Decision date	Oct 10, 1980
Days to decision	46 days
Third-party review	No

APPLICANT

Company	**Medspec Corp.**
Location	Mchenry, IL, US
510(k) history	15 submissions · 15 cleared · 1980-1981