FDA 510(k) Premarket Notification

K921417 URESIL LAPAROSCOPIC RETRACTOR

CLEARED

Oct 8, 1993
563 days to decision

K921417 · Product code: **HET** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k921417/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Mar 24, 1992
Decision date	Oct 8, 1993
Days to decision	563 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Uresil Corp.**
Location	Mchenry, IL, US
Contact	LEV MELINYSHYN
510(k) history	45 submissions · 44 cleared · 1981-2001