FDA 510(k) Premarket Notification

K912060 MENTOR BLACK LIGHT INJECTION STENT SET

CLEARED

Sep 27, 1991
141 days to decision

K912060 · Product code: **FAD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k912060/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	May 9, 1991
Decision date	Sep 27, 1991
Days to decision	141 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Mentor Corp.**
Location	Mchenry, IL, US
Contact	BYRON H.WICKETT
510(k) history	61 submissions · 61 cleared · 1977-2013

Mentor Corp. is a surgical aesthetics and medical device company based in McHenry, US. Now part of Johnson & Johnson MedTech, the brand supplies products to plastic surgeons and specialists worldwide. Mentor has received FDA 510(k) clearances from total submissions since its first clearance in 1977. The company's regulatory record spans General & Plastic Surgery, Gastroenterology & Urology, Obstetrics & Gynecology, and Radiology device categories. The latest clearance was recorded in 2013, reflecting the company's historical significance in surgical device innovation. Men...