

K163090 Plasma Edge SystemMay 23, 2017
200 days to decisionK163090 · Product code: **FAS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k163090/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrosurgical, Active, Urological (FAS)
Date received	Nov 4, 2016
Decision date	May 23, 2017
Days to decision	200 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Chirurgie Innovation
Location	Massy, FR
Contact	Guillaume Noury
510(k) history	2 submissions · 2 cleared · 2017-2022

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