

K213818 VersaOne Optical Trocar with Fixation Balloon Cannula, VersaOne Universal Fixation Balloon CannulaJun 27, 2022
202 days to decisionK213818 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k213818/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Dec 7, 2021
Decision date	Jun 27, 2022
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Covidien
Location	North Haven, CT, US
Contact	Michael Mach
510(k) history	130 submissions · 126 cleared · 2008-2024

Covidien is an Irish-registered global healthcare products company headquartered in North Haven, Connecticut. Now part of Medtronic following a 2015 acquisition, the brand continues to operate as a major medical device manufacturer. Covidien maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions spanning 2008 to 2024. The company specializes in General & Plastic Surgery devices, with a dominant focus on surgical staplers, sutures, and wound closure systems. Recent clearances include advanced stapling technologies, endotracheal tubes, a...