

K260649 OES ELITE Cystoscope and AccessoriesMay 21, 2026
83 days to decisionK260649 · Product code: **FAJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k260649/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Feb 27, 2026
Decision date	May 21, 2026
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Obturator, 17 Fr. (WA2C17BO); Obturator, 19.8 Fr. (WA2C19BO); Obturator, 21 Fr. (WA2C21BO); Obturator, 21 Fr., for sheath with ramp (WA2C21RO); Obturator, 21 Fr., long (WA2C21LO); Obturator, 21 Fr., for straight sheath (WA2C21SO); Obturator, 22.5 Fr. (WA2C22BO); Obturator, 25 Fr. (WA2C25BO); Obturator, optical, 19.8 Fr. (WA2C19BV); Obturator, optical, 21 Fr. (WA2C21BV); Obturator, optical, 21 Fr., for straight sheath (WA2C21SV); Obturator, optical,

APPLICANT

Company	Olympus Winter & Ibe GmbH
Location	Melville, NY, US
Contact	Daria Schuriner
510(k) history	43 submissions · 43 cleared · 1997-2026

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