

K190378 Spirotome Endo 08 Gauge, Spirotome Endo 10 Gauge, Spirotome Endo 14 Gauge, Spirotome Endo 14 Gauge with 10 mm Helix

May 24, 2019
94 days to decision

K190378 · Product code: **KNW** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k190378/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Feb 19, 2019
Decision date	May 24, 2019
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bioncise NV
Location	Wellen, BE
Contact	Jaak Janssens
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k190378/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026