

**K083720 OSSEODUO, SHAVER HANDPIECE S80 AND S120,
MICROMOTOR 80K**Mar 20, 2009
95 days to decisionK083720 · Product code: ERL · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k083720/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Dec 15, 2008
Decision date	Mar 20, 2009
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bien-Air Surgery SA
Location	Le Noirmont, CH
Contact	HUGUES FROIDEVAUX
510(k) history	5 submissions · 5 cleared · 2009-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083720/> 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 May 25, 2026