

K150969 Unidrive S III ENT 40701601-1 with KARL STORZ-SCB, DrillCut-X II Shaver Handpiece, High Speed EC Micromotor II for use with INTRA Drill Handpieces

Jan 8, 2016
270 days to decision

K150969 · Product code: ERL · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k150969/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Apr 13, 2015
Decision date	Jan 8, 2016
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	KARL STORZ Endoscopy-America, Inc.
Location	Mchenry, IL, US
Contact	Jennifer Michelle Chambers
510(k) history	361 submissions · 361 cleared · 1980-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k150969/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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