FDA 510(k) Premarket Notification

# K232015 ATMOS Scope (507.7000.0)

**CLEARED**

Aug 3, 2023
28 days to decision

K232015 · Product code: **EOB** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k232015/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Nasopharyngoscope (flexible Or Rigid) (EOB) |
| Date received | Jul 6, 2023 |
| Decision date | Aug 3, 2023 |
| Days to decision | 28 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | ATMOS Scope Pro (507.7050.0); ATMOS Scope iPrime (507.7060.0) |

## APPLICANT

| | |
|---|---|
| Company | **Atmos Medizintechnik GmbH & Co. KG** |
| Location | Lenzkirch, DE |
| Contact | Reinhold Storch |
| 510(k) history | 2 submissions · 2 cleared · 2023-2025 |