

K953161 MAICO MA630D AUDIOMETER WITH OPTIONAL REFLEX DECAY & EUSTACHIAN TUBE FUNCTIONJul 24, 1995
17 days to decisionK953161 · Product code: ETY · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k953161/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tester, Auditory Impedance (ETY) |
| Date received | Jul 7, 1995 |
| Decision date | Jul 24, 1995 |
| Days to decision | 17 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Maico Hearing Instruments, Inc. |
| Location | Mchenry, IL, US |
| Contact | MIKE CZURA |
| 510(k) history | 58 submissions · 57 cleared · 1977-1996 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953161/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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