

**K951324 MAXOL IMAGE II PATIENT MATCHED BREAST
PROSTHESIS**May 26, 1995
64 days to decisionK951324 · Product code: **KCZ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k951324/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Breast, External, Used With Adhesive (KCZ) |
| Date received | Mar 23, 1995 |
| Decision date | May 26, 1995 |
| Days to decision | 64 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Maxol Limited L.C. |
| Location | Overland Park, KS, US |
| Contact | MARK SCHANZE |
| 510(k) history | 1 submissions · 1 cleared · 1995-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k951324/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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