

**K001958 KEYSTONE MEDICAL SCHON XL SOFT-LINE DOUBLE
LUMENT CATHETER. KEYSTONE MEDICAL 12 F DUO-FLOW
AND 14F DUO-FLOW 400 XL CATH**Sep 25, 2000
90 days to decisionK001958 · Product code: **MPB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k001958/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Hemodialysis, Non-implanted (MPB) |
| Date received | Jun 27, 2000 |
| Decision date | Sep 25, 2000 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Keystone Medical |
| Location | Great Neck, NY, US |
| Contact | ALAN P SCHWARTZ |
| 510(k) history | 2 submissions · 2 cleared · 2000-2001 |

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