

K911587 K-SOL(TM)Nov 1, 1991
206 days to decisionK911587 · Product code: **KDN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k911587/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Perfusion, Kidney (KDN) |
| Date received | Apr 9, 1991 |
| Decision date | Nov 1, 1991 |
| Days to decision | 206 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Alcon Laboratories |
| Location | Mchenry, IL, US |
| Contact | DENISE E MCEACHERN |
| Website | https://www.alcon.com |
| 510(k) history | 47 submissions · 47 cleared · 1976-2007 |

Alcon Laboratories is a Swiss-American pharmaceutical and medical device company specializing in eye care products. The company maintains operational headquarters in Fort Worth, Texas, with a significant global presence in eye care innovation. Alcon has received FDA 510(k) clearances from total submissions since its first clearance in 1976. The company's regulatory portfolio is dominated by Ophthalmic devices, which account for 74% of all submissions. The latest clearance on record dates to 2007, reflecting the company's historical significance in the medical device regul...