

K914251 MODEL IRC PASSPORT NEBULIZERJan 24, 1992
123 days to decisionK914251 · Product code: **LAW** · Toxicology
Source: <https://www.510kdatabase.net/k914251/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Theophylline Control Materials (LAW) |
| Date received | Sep 23, 1991 |
| Decision date | Jan 24, 1992 |
| Days to decision | 123 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Invacare Corp. |
| Location | Elyria, OH, US |
| Contact | EDWARD A KROLL |
| Website | http://www.invacare.com/ |
| 510(k) history | 111 submissions · 110 cleared · 1980-2007 |

Invacare Corp. is a healthcare company headquartered in Elyria, Ohio, specializing in mobility and respiratory care solutions. The company develops healthcare and lifestyle products focused on safety, quality, and performance for users with reduced movement. Invacare has received FDA 510(k) clearances from total submissions since its first clearance in 1980. The company's cleared devices span Physical Medicine and anesthesiology categories, including power wheelchairs, mobility scooters, standing devices, and respiratory masks. The latest FDA 510(k) clearance was in 2007,...
