FDA 510(k) Premarket Notification

# K852310 NATURALYTE BICARBONATE CONCENTRATE-DRY PACK

**CLEARED**

Jul 26, 1985
58 days to decision

K852310 · Product code: **FKQ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k852310/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Dialysate Delivery, Central Multiple Patient (FKQ) |
| Date received | May 29, 1985 |
| Decision date | Jul 26, 1985 |
| Days to decision | 58 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Erika, Inc.** |
| Location | Mchenry, IL, US |
| Contact | DEL DONNA |
| Website | https://www.erika.com |
| 510(k) history | 43 submissions · 43 cleared · 1976-1985 |

Erika, Inc. is a medical device company based in McHenry, US. The company specialized in Gastroenterology & Urology devices. Erika, Inc. received FDA 510(k) clearances from total submissions between 1976 and 1985. The company's regulatory focus centered on Gastroenterology & Urology devices, which represented 86% of its submission portfolio. Notable cleared products included infusion pump administration sets, artificial kidney filtration systems, and bicarbonate concentrate formulations. This company is inactive and represents a historical regulatory record. No FDA 510(k)...