FDA 510(k) Premarket Notification

K880829 GDS ENZYMATIC ACETAMINOPHEN REAGENT

CLEARED

May 27, 1988
87 days to decision

K880829 · Product code: **LDP** · Toxicology
Source: https://www.510kdatabase.net/k880829/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetry, Acetaminophen (LDP)
Date received	Mar 1, 1988
Decision date	May 27, 1988
Days to decision	87 days
Third-party review	No

APPLICANT

Company	**Gds Technology, LLC**
Location	Elkhart, IN, US
Contact	DE CASTRO
510(k) history	7 submissions · 7 cleared · 1988-2000