K030460 MODIFICATION TO BRENNEN BIOSYNTHETIC SURGICAL MESH MATRIX

CLEARED

Mar 7, 2003
23 days to decision

K030460 · Product code: **PAG** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k030460/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Non-synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (PAG)
Date received	Feb 12, 2003
Decision date	Mar 7, 2003
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Brennen Medical, Inc.**
Location	St, Paul, MN, US
Contact	KENNETH B HERLAND
510(k) history	17 submissions · 16 cleared · 1994-2006

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k030460/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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