

K251403 Dornier Bi-Polar Electrode BIP12CLM Bipolar 12° Medium Cutting Loop 24 Fr Electrode-Sterile, Single-Use BIP12CLL Bipolar 12° Large Cutting Loop 24 Fr Electrode-Sterile, Single-Use BIP30CLM Bipolar 30° Medium Cutting Loop 24 Fr Electrode-Sterile, Single-Use BIP30CLL Bipolar 30° Large Cutting Loop 24 Fr Electrode-Sterile, Single-Use BIPMBLA Bipolar Medium Bladder Loop 24 Fr Electrode-Sterile, Single-Use BIPNEEL Bipolar Needle 24 Fr Electrode-Sterile, Single-Use BIPDDSC Bipolar Disc)

Dec 5, 2025
213 days to decision

K251403 · Product code: FAS · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k251403/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrosurgical, Active, Urological (FAS)
Date received	May 6, 2025
Decision date	Dec 5, 2025
Days to decision	213 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dornier Medtech America Inc (Dmta)
Location	Kennesaw, GA, US
Contact	John Hoffer
510(k) history	1 submissions · 1 cleared · 2025-2025
