

FDA Clearance Summary – PRECISION by K.

This document confirms that PRECISION by K. PDO threads are FDA-cleared as a Class II absorbable surgical suture under the manufacturer Dongwon Medical Co., Ltd. The following information is extracted directly from the FDA Establishment Registration & Device Listing database.

Field	Details
Product Name	PRECISION by K.
Device Classification	Class II – Suture, Surgical, Absorbable, Polydioxanone (Product Code: NEW)
Regulation Number	21 CFR 878.4840
510(k) Number	K160761
Manufacturer	Dongwon Medical Co., Ltd.
Establishment Number	3013529787
Last FDA Update	August 11, 2025
FDA Listing Link	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/rl.cfm?lid=516308&lpcd=NEW

For further verification, the FDA listing can be accessed directly through the provided link above. This document is intended for distributor verification purposes only.