

# K153606 LENS Camera Control Unit-WiFi, LENS Camera Unit-Non-WiFi, LENS camera head, Camera Coupler, Tablet Application

Jun 2, 2016  
168 days to decision

K153606 · Product code: **GCJ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k153606/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Dec 17, 2015
Decision date	Jun 2, 2016
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Smith &amp; Nephew</b>
Location	Memphis, TN, US
Contact	JANICE HASELTON
Website	<a href="http://www.smith-nephew.com/">http://www.smith-nephew.com/</a>
510(k) history	17 submissions · 17 cleared · 2015-2025

Smith & Nephew is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in Memphis, US, and serves approximately 100 countries worldwide. The company has received FDA 510(k) clearances from total submissions since 2015. Orthopedic devices represent the dominant category, including pelvic and acetabular systems, patella plates, suture anchors, cable systems, external fixators, arthroscopes, and limb lengthening systems. The latest clearance was granted in 2025, confirming a...