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Establishment Registration & Device Listing

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Proprietary Name:	Arthroscopic Accessories; Cubital Tunnel Release System; EGR System; EndoRelease Endoscopic; Endoscopic Gastroc Release System
Classification Name:	ACCESSORIES,ARTHROSCOPIC
Product Code:	NBH
Device Class:	1
Regulation Number:	888.1100
Medical Specialty:	Orthopedic
Registered Establishment Name:	INTEGRA LIFESCIENCES CORPORATION
Registered Establishment Number:	3004608878
Owner/Operator:	INTEGRA LIFESCIENCES CORPORATION
Owner/Operator Number:	9004007
Establishment Operations:	Manufacturer

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Product Classification

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Device	Accessories,Arthroscopic
Regulation Description	Arthroscope.
Regulation Medical Specialty	Orthopedic
Review Panel	Orthopedic
Product Code	NBH
Submission Type	510(K) Exempt
Regulation Number	888.1100
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. it is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

if a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the u.s. however, these manufacturers are required to register their establishment. please see the registration and listing website for additional information.

Third Party Review	Not Third Party Eligible