



FDA Information

Quantum

Device Classification Name: Electrosurgical, cutting & coagulation & accessories
510(k) Number: K131696
Device Name: Vesalius (Quantum)
Applicant: TELEA ELECTRONIC ENGINEERING SRL
VIA LEONARDO DA VINCI 13
Sandrigo, IT 36066
Regulation Number: 878.4400
Regulation Medical Specialty: General & Plastic Surgery

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2018]
[CITE: 21CFR878.4400]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER H--MEDICAL DEVICES

PART 878 -- GENERAL AND PLASTIC SURGERY DEVICES

Subpart E--Surgical Devices

Sec. 878.4400 Electrosurgical cutting and coagulation device and accessories.

(a) *Identification.* An electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current.

(b) *Classification.* Class II.

Indications for Use

510(k) Number (if known): K131696

Device Name: Vesalius, models Vesalius MCNplus and QUANTUM

Indications for Use:

The Vesalius, models Vesalius MCNplus and QUANTUM and accessories are intended for resection, ablation and coagulation of soft tissues and haemostasis of blood vessels in surgical procedures in orthopaedic, arthroscopic, neurosurgery, ENT, and spinal procedures.

Prescription Use

AND/OR

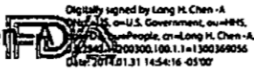
Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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Long H. Chen



for BSA

(Division Sign-off)

Division of Surgical Devices

510(k) Number: K131696