FDA Information
Essential

Device Classification Name:	Electrosurgical, cutting & coagulation & accessories
510(k) Number:	K152933
Device Name:	Vesalius (Essential)
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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K152933

Device Name
Vesalius, model Essential

Indications for Use *(Describe)*

The Vesalius Essential device and its accessories are intended for resection, ablation and coagulation of soft tissues and haemostasis of blood vessels in surgical procedures in orthopedic, arthroscopic, neurosurgery, ENT, and spinal procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)