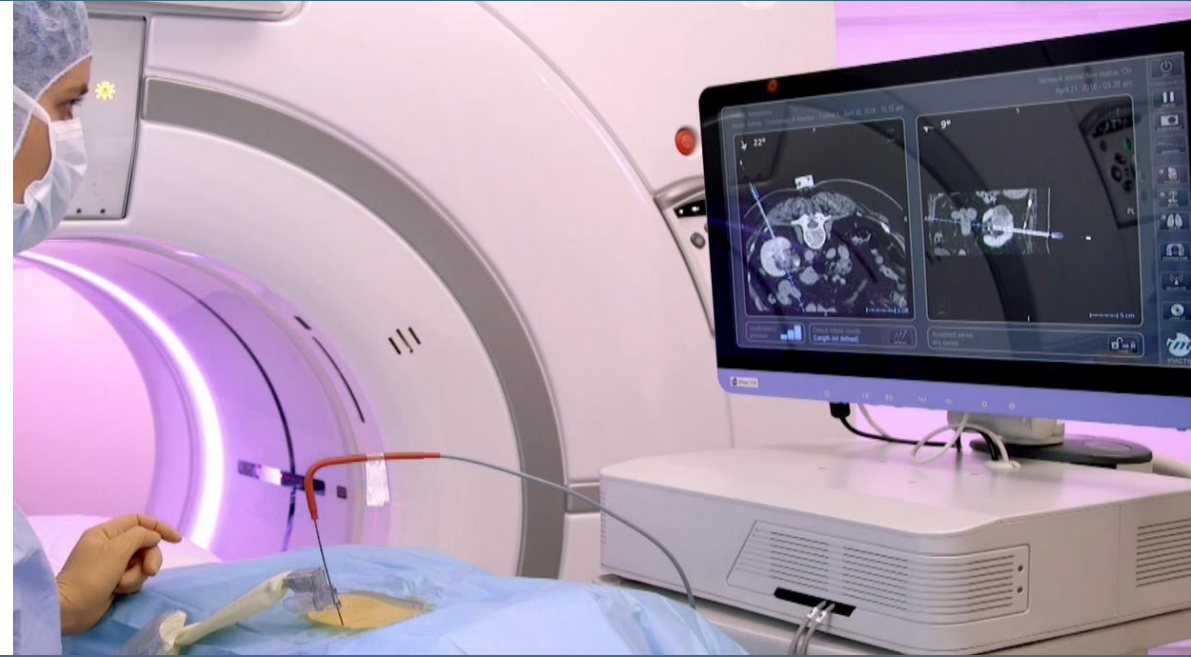
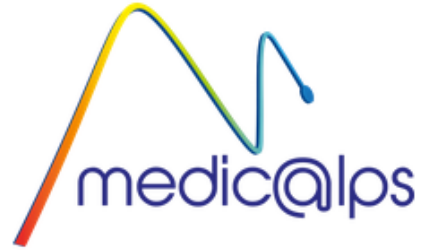




IMACTIS®

Georges Tabary CEO pour



TEMOIGNAGE USA

Qui?

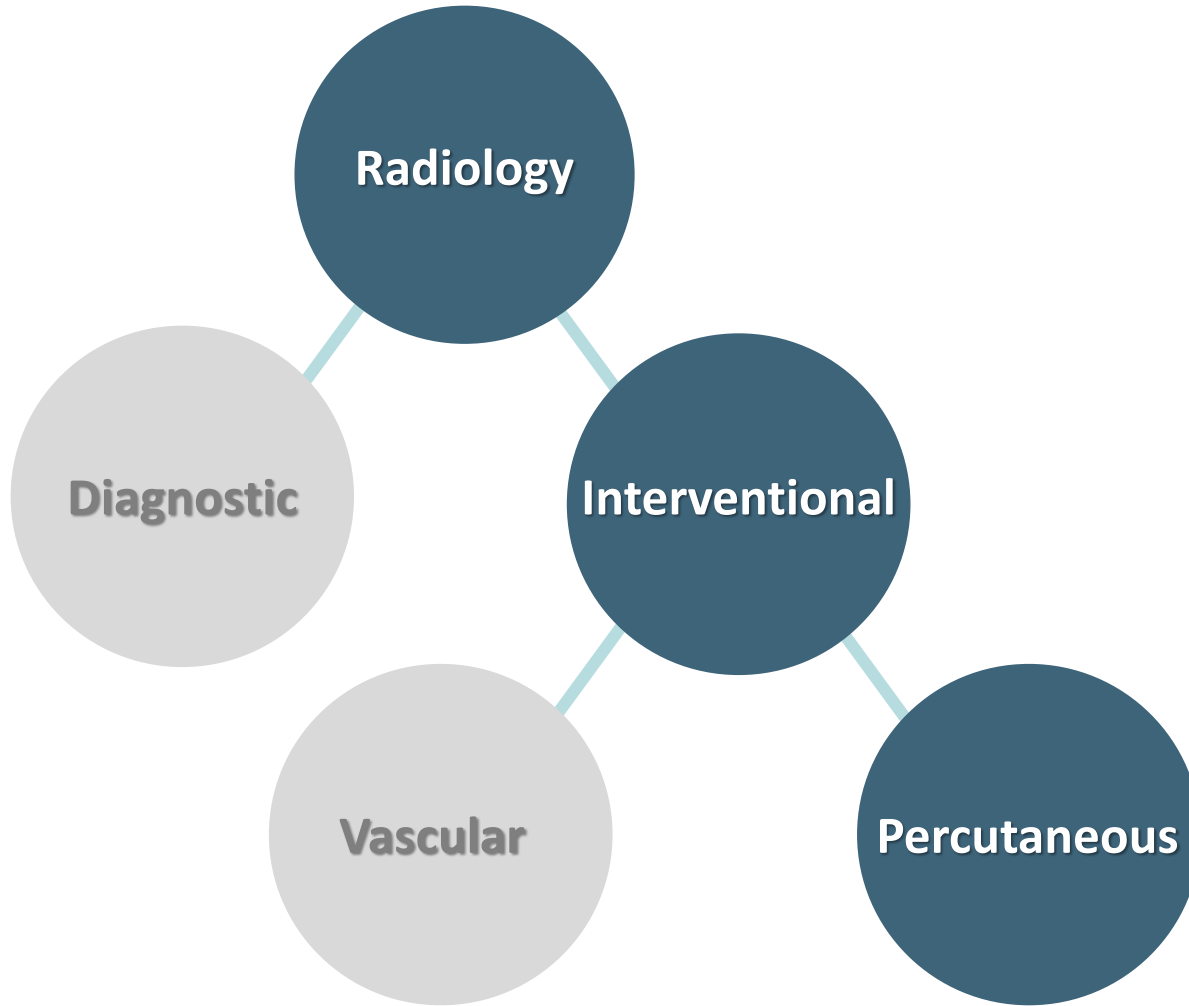
CT-navigation™, l'excellence en radiologie interventionnelle

Chez Imactis, nous croyons dans le pouvoir de l'innovation en radiologie interventionnelle, au bénéfice des patients comme des praticiens: des procédures mini-invasives, pour une meilleure qualité de vie.

Les valeurs de notre équipe incluent la diversité, la complémentarité et le dépassement de soi. Ensemble, nous sommes engagés à fournir des solutions pratiques, efficaces et innovantes, qui contribueront à l'amélioration des soins.



Percutaneous Interventional Radiology

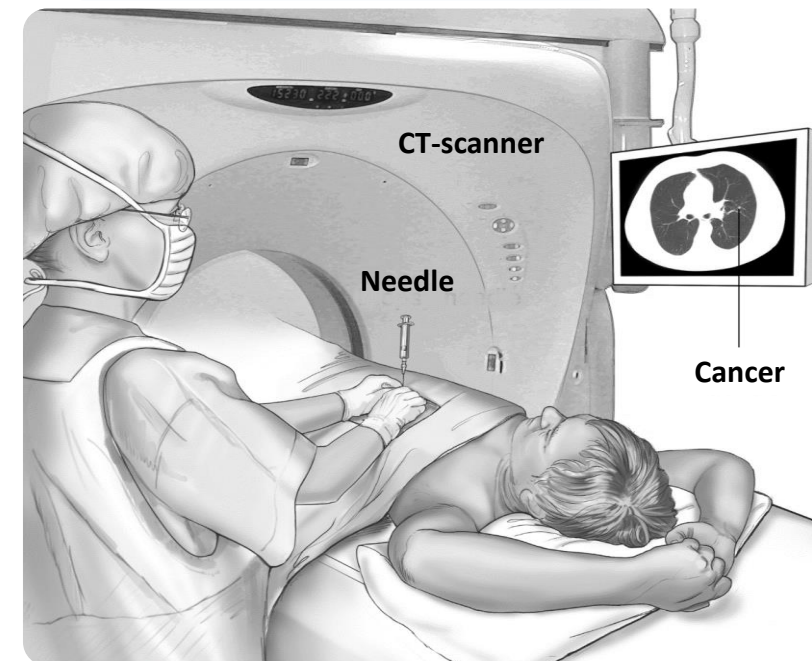


Biopsy

Infiltration

Vertebroplasty

Tumor ablation



2018: obtention du 510(k) FDA



IMACTIS® SAS
% Mady Batailh
Quality Manager
5 avenue du Grand Sablon
38700 La Tronche
FRANCE

April 24, 2018

Re: K162314
Trade/Device Name: IMACTIS CT-NAVIGATION system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: April 13, 2018
Received: April 16, 2018

Dear Mady Batailh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

2019 congress attendance

① March 24-28
SIR 2019, Austin TX



② April 8-11 **ECIO 2019**
ECIO 2019, Amsterdam NL
• Workshop 'Navigation & thermoablation'

③ June 7-11
WCIO, Boston, MA
• World Conference on Interventional Oncology



④ Sept. 7-11
CIRSE, Barcelona, SP



- **USER MEETING**
- Cardiovascular and Interventional Radiological Society of Europe
- IMACTIS abstracts submitted

⑤ June 11-13
IGR, Paris



⑥ October 12-15
JFR, Paris
• Journées Francophones de Radiologie



⑦ December 1-6
RSNA, Chicago, IL
• Radiological Society of North America
• Imactis abstract submitted

