

Update from Center for Devices & Radiologic Health (CDRH)

Tara A. Ryan, MD, MS, MBA
Center for Devices & Radiologic Health
Office of Device Evaluation



I have no relevant financial information to report.



Types of Devices

- □ **Diagnostic** *in vitro* diagnostic device or an imaging tool that provides essential information to the clinician.
- □ Therapeutic includes devices often used in combination with chemotherapy.
- □ Palliative relief of symptoms and improvement in quality of life.

BRCA1 and BRCA2 Diagnostic





23and Me – Genetic Health Report



Targeted Therapeutic



Companion Diagnostic







- □ Foundation Medicine CDx tests 324 genes in solid tumors
- □ OncomineTM Dx Target Test Extended RAS Panel in vitro diagnostic for patients with non-small cell lung cancer (NSCLC).
- □ ClonoSEQ assay measures amount of cancer cells remaining in bone marrow of patients with acute lymphoblastic leukemia (ALL) or multiple myeloma.



Diagnostic Devices (cont.)



Magtrace[™] and Sentimag® Magnetic Localization System



Diagnostic Devices (cont.)



Mammography - Self-Compression



Tumor Ablation Technologies



- □ Radiofrequency Ablation (RFA)
- □ Microwave Ablation
- □ Laser ablation
- □ High-intensity focused ultrasound (HIFU) ablation
- Cryoablation



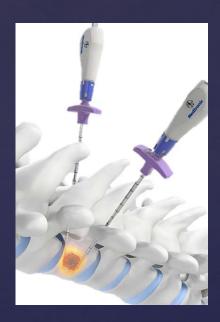
Therapeutic Devices (cont.)



Optune® - for treatment of a type of brain cancer called glioblastoma multiforme (GBM)



Palliative Devices



OsteoCool™ RF Ablation System



2018 FDA update on BIA- ALCL

- PROFILE collects real world data regarding patients who have a confirmed diagnosis of BIA-ALCL.
- Post-market studies/MDRs
- National Breast Implant Registry (NBIR)
- FDA will hold a public meeting of the General and Plastic Surgery Devices Panel of our Medical Devices Advisory Committee in 2019

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620589.htm



Thank you



Tara A. Ryan, MD, MS, MBA
Food & Drug Administration
Center for Devices & Radiologic Health
Tara.Ryan@fda.hhs.gov