

# Update from Center for Devices & Radiologic Health (CDRH)

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**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

## Personalized Medicine

Targeted  
Therapeutic



Companion  
Diagnostic



## New Companion Diagnostic Devices

- ❑ **Foundation Medicine CDx** – tests 324 genes in solid tumors
- ❑ **Oncomine™ 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>

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm>

# Thank you



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