



Update from Center for Devices & Radiologic Health (CDRH)

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**Office of Device
Evaluation
(ODE)**

**Division of
Cardiovascular Devices
(DCD)**

**Division of
Anesthesiology, General
Hospital, Respiratory,
Infection Control, and
Dental Devices (DAGRID)**

**Division of Surgical
Devices (DSD)**

**Division of
Neurological And
Physical Medicine
Devices (DNPMD)**

**Division of Ophthalmic
and Ear, Nose, and
Throat Devices (DOED)**

**Division of Reproductive,
Gastro-Renal, and
Urological Devices
(DRGUD)**

**Division of Orthopedic
Devices (DOD)**

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.

Personalized Medicine

Targeted
Therapeutic



Companion
Diagnostic



Companion Diagnostic Devices

- **PD-L1 assays pharmDx** – to choose best treatment for melanoma and non-small cell lung cancer.
- **RealTime DH2 assay**- to detect specific mutations in patient with AML
- **ClearLLab reagents flow cytometric test system** - first agency authorized test for use with flow cytometry to aid in the detection of several leukemias and lymphomas

Diagnostic (cont.)



VELscope® Vx - Screening for Oral Cancer

Diagnostic (cont.)



QuantX - Assessment of breast lesions

Diagnostic (cont.)



Nevisense - diagnostic support tool for non-visual detection of malignant melanoma.

Therapeutic

Tumor Ablation Technologies

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

Therapeutic (cont.)



Optune® - for treatment of a type of brain cancer

Therapeutic (cont.)



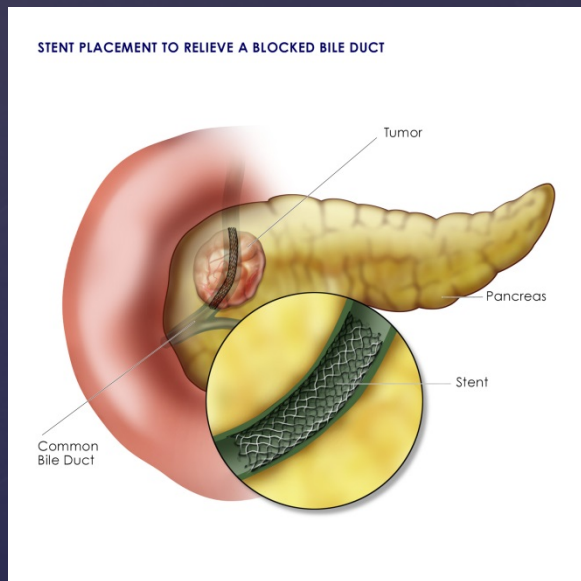
DigniCap Scalp Cooling System - Reduces chemotherapy-induced hair loss

Therapeutic (cont.)

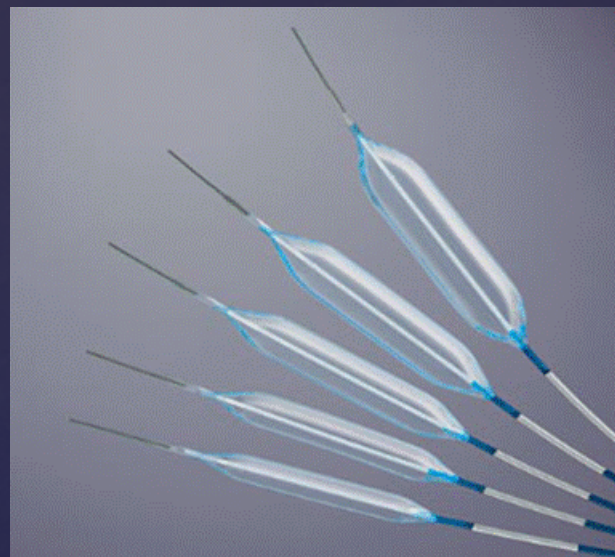


Proton Therapy

Palliative Devices



Stents



Dilatation Balloons

Palliative Devices (cont.)



Intrathecal pain pumps

Devices in Clinical Trials

- Systems that provide real-time tissue classification during prostate biopsies.
- Use of electric fields for the treatment of non-small cell lung cancer (NSCLC)

Thank you



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