

Small Business, High Tech Development

CZT Detectors for Medical Imaging and Plant Biology

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QuadraSquare Inc.

Jefferson Lab, Tech Transfer Workshop
2018

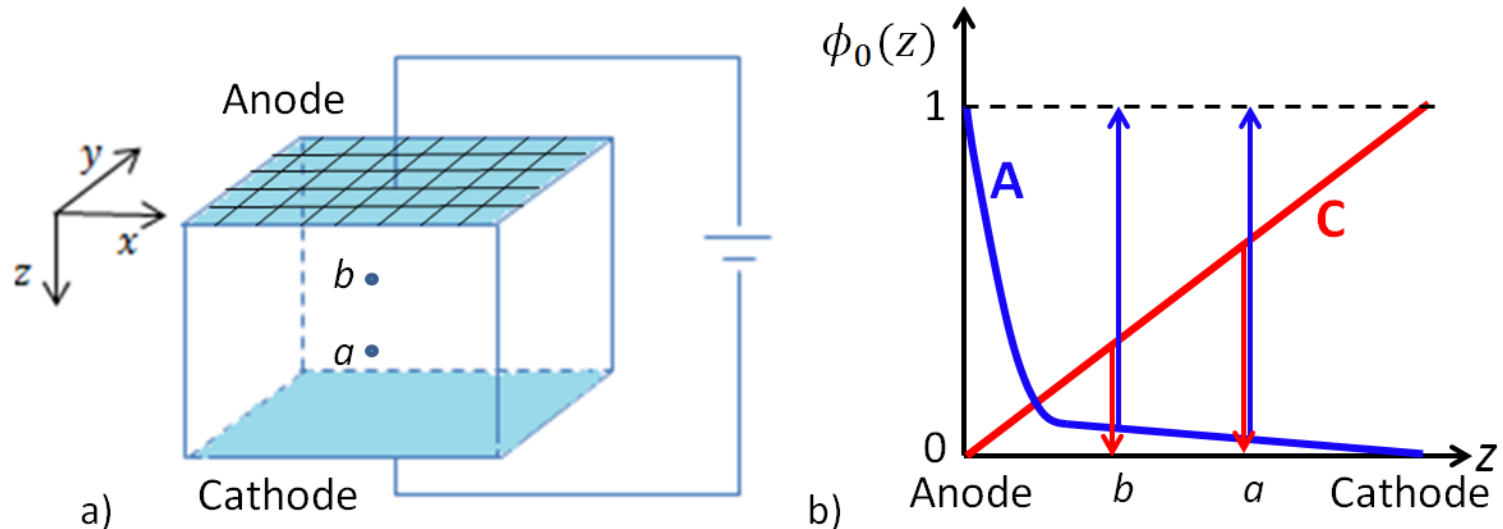
January 11, 2018

Outline

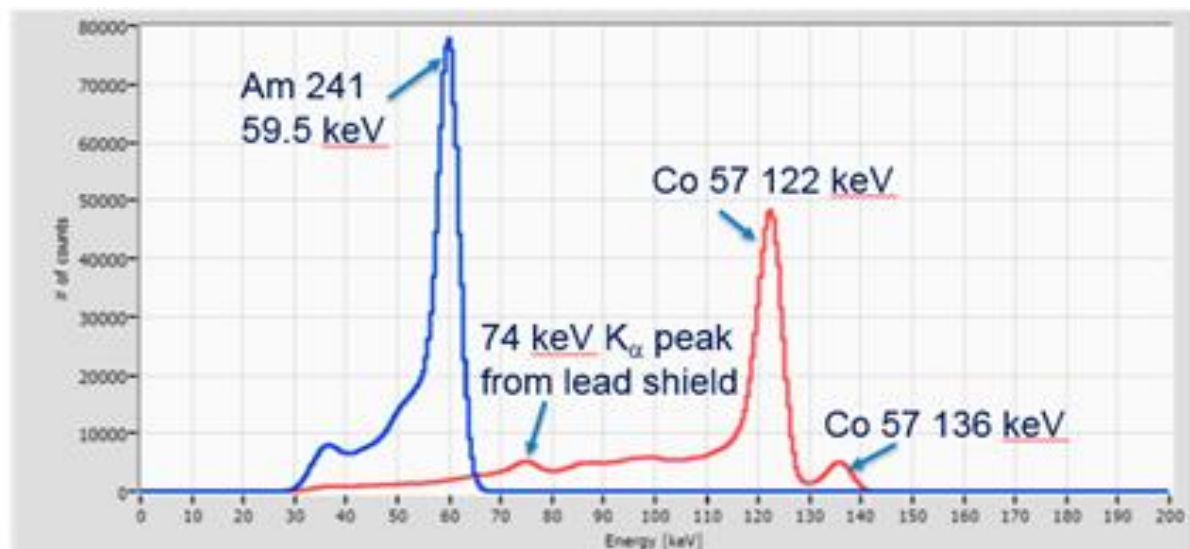
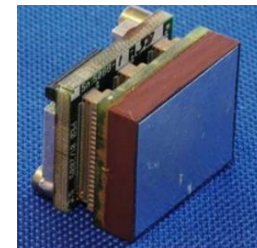
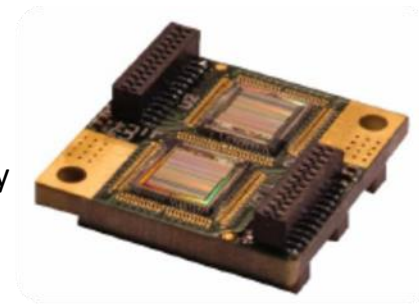
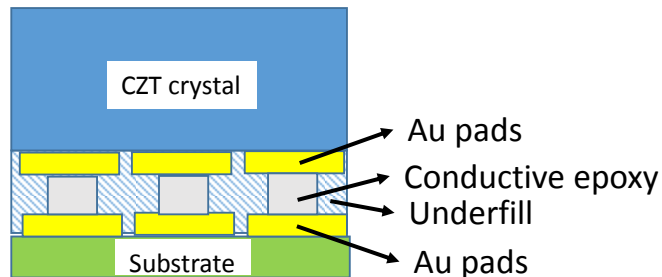
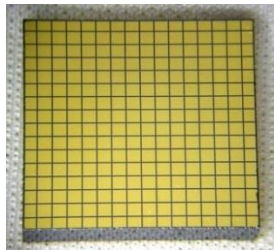
- **Scientific Section**
 - CZT detectors
 - Plant Imaging Applications
 - Medical Imaging - Molecular Breast Imaging
- **Business Section**
 - **Regulatory Considerations**
 - Quality Systems
 - FDA process
 - **Insurance Reimbursement Strategy**
 - CPT codes
 - CMS reimbursement
 - 3rd party insurance reimbursement
- **Finance Section**
 - Funding sources

CdZnTe semiconductor radiation detectors

- High voltage potential drop across crystal *causes induced charge in anode and cathode*.
- Unlike scintillating crystals, CZT crystals are not physically pixelated.



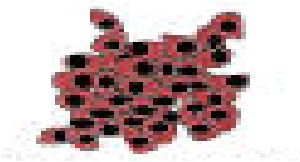
GammaMedica's CZT Detector



Molecular Breast Imaging



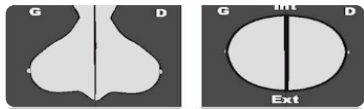
Patient receives a low dose injection of a radiotracer (e.g. Tc-99m Sestamibi)



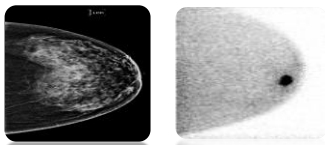
The tracer preferentially accumulates in cancer cells



The breast is minimally compressed between two digital gamma cameras

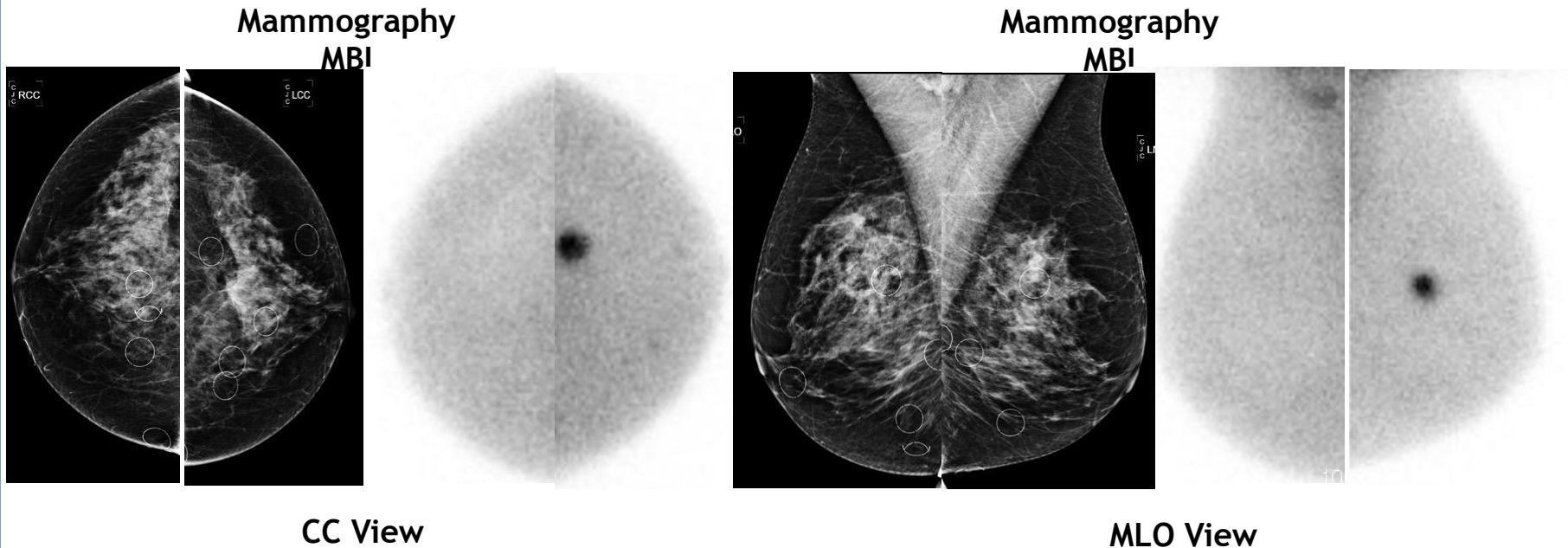


Imaging starts minutes post injection; acquires similar views of each breast as mammography



Images are presented in the same format as mammography making it easy to compare.

MBI Clinical Case: Dense Breast

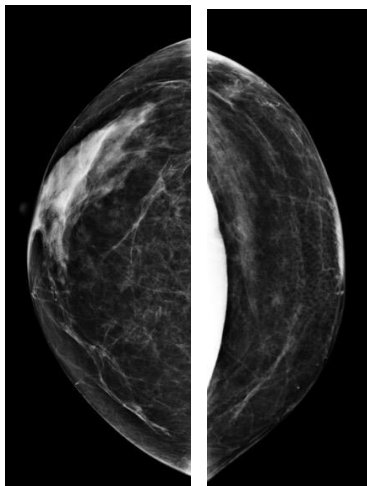


- Negative Mammogram
- MBI shows intense focal uptake in left breast
- Biopsy confirmed invasive ductal carcinoma

Images courtesy of Robin Shermis, MD, Promedica Toledo Hospital, Toledo, OH

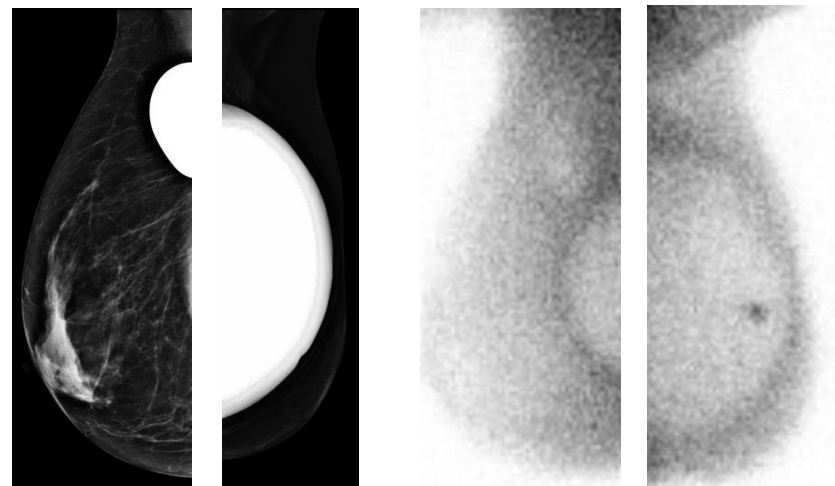
Clinical case: Breast Implant

Mammography
MBI



CC View

Mammography
MBI



MLO View

- Unable to displace left breast implant
- LumaGEM® shows uptake in area hidden by implant on mammography
- Biopsy positive for invasive ductal carcinoma

Images courtesy of Robbil Sheehy, MD, ProMedica Toledo Hospital, Toledo, OH

MBI Clinical Status

- FDA cleared MBI systems clinically
- Multiple clinical trial results show cancer detection sensitivity much better than mammography and ultrasound
- Low false positive rate -> few unnecessary biopsies
- American College of Radiology practice parameters for MBI released Oct 2017
- Mayo Clinic supplemental screening protocol for dense breasts recommends MBI

So what's the hold up?

- Perception of radiation induced cancer risk
 - MBI associated patient radiation dose 5x greater than mammography
 - Concerns with injecting radiation to healthy women for screening



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Regulatory Considerations



Electronic Code of Federal Regulations

e-CFR data is current as of **January 9, 2018**

[Title 21](#) → [Chapter I](#) → [Subchapter H](#)

TITLE 21—Food and Drugs

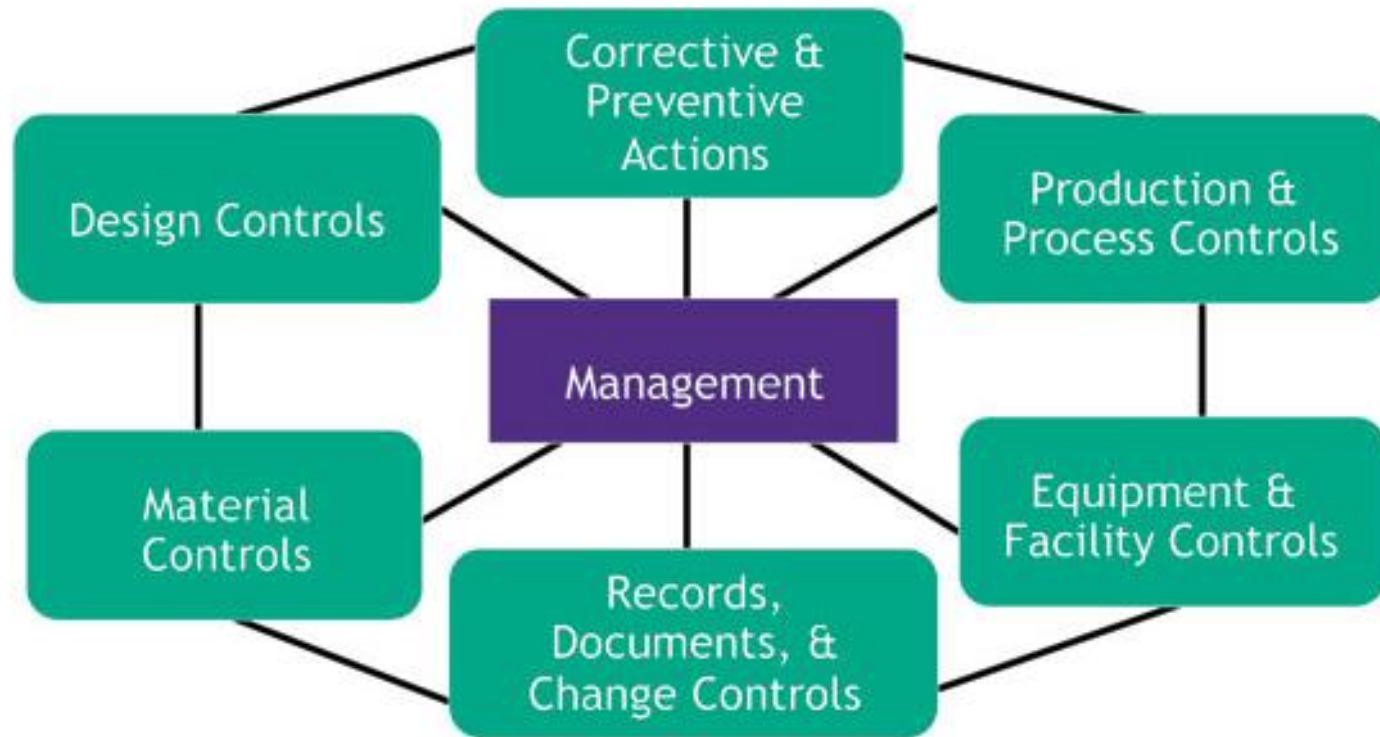
CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

SUBCHAPTER H—MEDICAL DEVICES

Part	Table of Contents	Headings
800	800.10 to 800.55	GENERAL
801	801.1 to 801.437	LABELING
803	803.1 to 803.58	MEDICAL DEVICE REPORTING
806	806.1 to 806.11	MEDICAL DEVICES: REPORTS OF CORRECTIONS

Quality System Regulation

CFR TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES
PART 820 QUALITY SYSTEM REGULATION



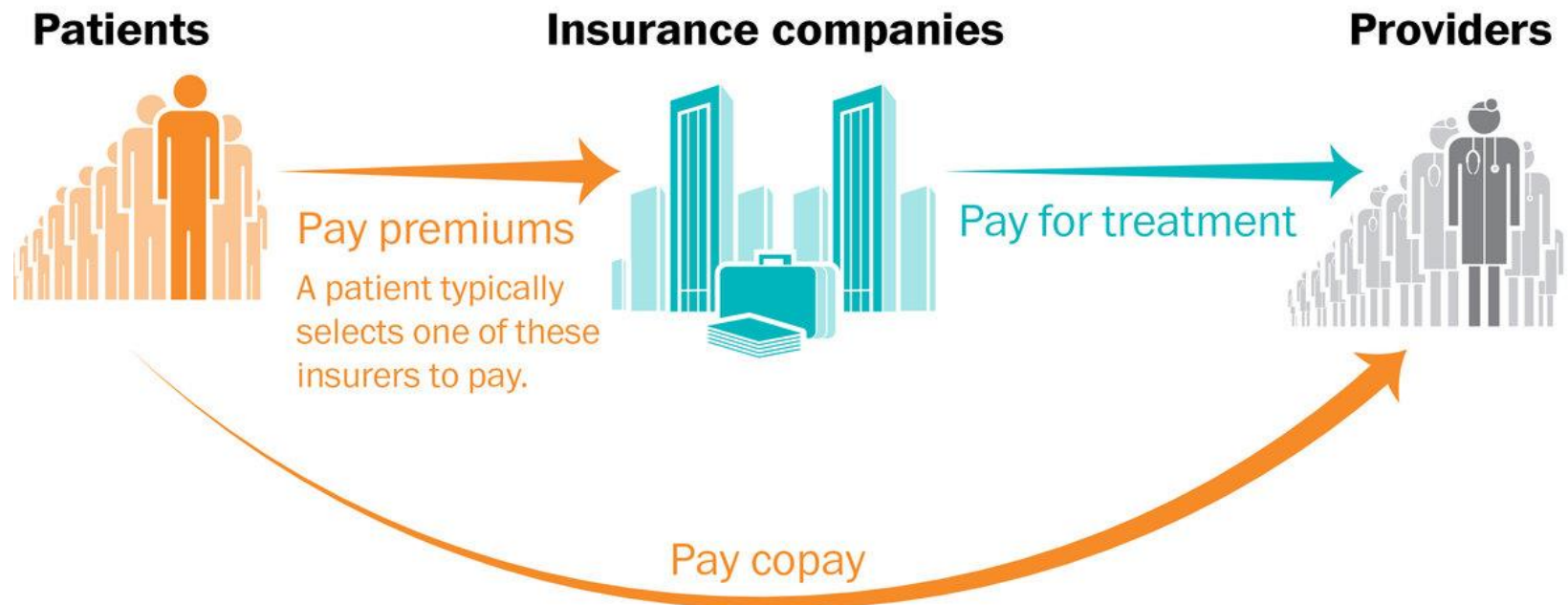
FDA classification and review

Category	Patient Risk	Examples	% devices	Review Type	Processing Time
Class 1	Low	<ul style="list-style-type: none">Elastic bandagesExamination glovesHandheld surgical instruments	67%	Labeling	< 3 months
Class II	Moderate	<ul style="list-style-type: none">Powered wheelchairsX-ray & MRI imagersSurgical drapes	31%	510(k) substantial equivalence	3 - 9 months
Class III	High	<ul style="list-style-type: none">Heart valvesSilicone breast implants	1%	PMA application	9+ months



Reimbursement Strategy

Medicare and other third-party health care payers are not required to cover every medical device that has been cleared or approved by the FDA



Current Procedural Terminology (CPT)

- CPT codes are published by the American Medical Association (AMA)
- A CPT code describes the medical procedures and services.
 - Category I - Well established medical procedures
 - Category II - Performance Measurement
 - Category III - Emerging Technology
- If a CPT code does not exist, then an application needs to be made to AMA to issue new code.
- AMA does not set the price amount for the code!

Reimbursement amounts

Medical device companies can apply for Medicare coverage of new devices requesting a national coverage determination (NCD) from CMS.

CMS make coverage decisions by determining whether the available evidence for a device supports the requested coverage.

Private insurance reimbursement rates (allowed amounts) are typically based off of CMS rates.

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Funding sources

Early stage - prototype development

- SBIRs (non-dilutive)
- Startup competitions
- Kick starter / crowd funding (Probably Not)

FDA Phase

- Angel investors - \$500K - \$5M (Longer Horizon)

Commercialization Phase

- Venture Capital investors - \$5M - \$15M (2 - 3 yr horizon)

- Strategic Partners, Tech Transfer Companies, Quadra Square





Thank you