



# Consideration of New Medical Technology

Kamran Aurang MD  
Orthopaedic Traumatologist  
Kaiser Permanente - Orange County

Robin Cisneros  
National Director, Medical Technology Assessment and Products

# Learning Objectives

- Understand how medical devices move through the FDA to the commercial market
  - Specific examples from orthopaedics
- Understand how KP considers new medical technology and products
  - Learn how you can provide input to KP's discussions and use internal resources to inform your practice

# How the FDA Regulates Medical Devices



## Center for Device and Radiologic Health (CDRH)

Classification

Approval

Data

# FDA Regulation of Medical Devices

## Classification of Medical Devices (I, II, and III)

Risk

Intended Use/Indications for Use

## Pathways to Market

Premarket Application (PMA)

Premarket Notification (510K)

Humanitarian Device Exemption (HDE)

# Device Classification

	<b>Class II</b> <b>Moderate Risk</b>	<b>Class III</b> <b>High Risk (or novel)</b>
	Electrocardiographs, power bone drills, mercury thermometers	Replacement heart valves, implantable stimulators, pacemakers
	Significant impact on patient care but not likely to cause direct serious injury	Support or sustain human life  Or, of substantial importance in preventing impairment of human health  Or, present a potential, unreasonable risk of illness or injury
	General and Special Controls	General controls and premarket application

# FDA Pathways to Market

Class II	Class III
<p>Require premarket notification of sale (510k)</p> <p>Some exceptions require PMA</p>	<p>Require PreMarket Approval (PMA)</p> <p>Some exceptions require 510k only</p>
<p>Relies on determination of substantial equivalence (SE) to a predicate device, an already approved, legally marketed device.</p> <p>If not SE, risk determines if process is PMA or 510(k).</p>	<p>Based on a determination that there is sufficient valid scientific evidence to reasonably assure that the device is safe and effective for its intended use.</p>
<p>Some clinical data may be provided</p>	<p>Clinical data required</p>



# 510k

Predicate devices can include products commercially distributed before the May 28, 1976, Medical Device Amendment.

A device is substantially equivalent if, in comparison to a predicate, it:

- has the same intended use as the predicate; **and**
- has the same technological characteristics as the predicate;
- If different technological characteristics:
  - does not raise new questions of safety and effectiveness; **and**
  - demonstrates that the device is at least as safe and effective as the legally marketed device.

# Premarket Approval (PMA)

Scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices

Most stringent marketing application required by FDA

Approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s)

FDA regulations provide 180 days to review the PMA

An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device

# Another Path to Market: Humanitarian Device Exemption (HDE)

- Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the US per year.
- Submission of an HDE application, is similar in both form and content to a premarket approval (PMA) application, but is exempt from effectiveness requirements of a PMA.
- An HDE authorizes marketing of the HUD
- Clinical use of an HUD requires IRB approval and the IRB may superimpose additional regulations

# Humanitarian Device Exemption (HDE)

- Device does not pose an unreasonable or significant risk of illness or injury
- Probable benefit to health outweighs the risk of injury or illness from its use
- No comparable devices are available to treat or diagnose the disease or condition
- The IRB can approve the use of an HUD only for the FDA-authorized indications of the device

# A Closer Look at the FDA and Approved Devices

## **The Government Accountability Office (GAO) Report on the FDA's Medical Device Approval Process (January 2009)**

- Number, type, and attributes of PMA and 510k approvals
- Laws and regulations concerning the review process
- Did not examine potential harms the devices approved by the less stringent process may have caused

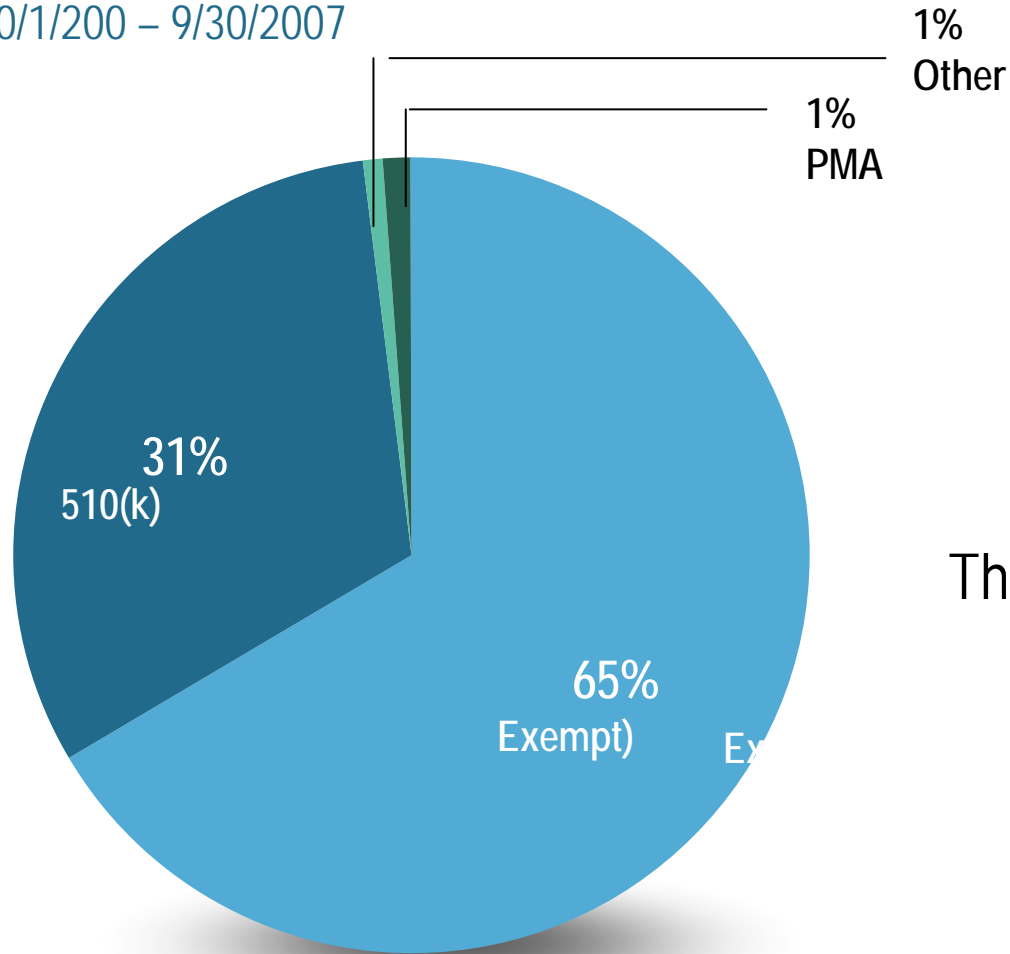
# A Closer Look at the FDA and Approved Devices

2003-2007, fiscal Per 2009 GAO report	Class I & II Approvals	Class III Approvals
510K	11,935 (90% of submissions)	228 (67% of submissions)
Original PMA		170 approvals (78% of submissions)

More Class III devices were FDA approved through the 510(k) pathway than through an original PMA submission.

# Devices Listed with FDA

10/1/200 – 9/30/2007



The pie represents a total of 50,189 devices.

95% of exempt devices are Class I. The remaining 5% are class II.

# The Challenges

- Relatively very few products receive PMA meaning little clinical data accompanies new products to market
- Existing clinical data may not be published in a peer-reviewed medical journal and if the data was produced for a 510k, may be difficult to find at all
- Physicians are faced with making decisions about products with imperfect, if not biased, information

# How KP Assesses New Medical Devices



Evidence Analysis  
Access and Pricing  
Registry

# Why Isn't the FDA Enough?

## FDA Interests

- Safety
- Efficacy
  - Benefit of using a technology for a particular health problem in ideal conditions
- Substantial Equivalence or comparison to placebo
- Intermediate, short-term outcomes

## KP's Interests

- Everything to the left PLUS
- Effectiveness
  - Benefit of using a technology for a particular health problem in general or routine conditions
- Comparison to standard of care and relevance to KP membership
- Long term health outcomes
- Operational impact

# Answering KP's Questions

- Safety and Efficacy
- Effectiveness
  - Benefit of using a technology for a particular health problem in general or routine conditions
- Comparison to standard of care and relevance to KP membership
- Long term health outcomes
- Operational impact

Interregional New Technologies  
Committee  
(INTC)

National Product Council  
(NPC)

Interregional Implant Registry  
Committee  
(IIRC)

# Answering KP's Questions: The Evidence



- 18 members, >50% MDs
- Interregional and Inter-entity
- Monitors new technology
- Evaluates
  - Safety, Efficacy, Effectiveness
- Recommends to inform
- 23 topics in 2009
- Internal and external reviews
- PMG expert opinion for all topics
- Collaborates with NPC and IIRC

Interregional New Technologies  
Committee  
(INTC)

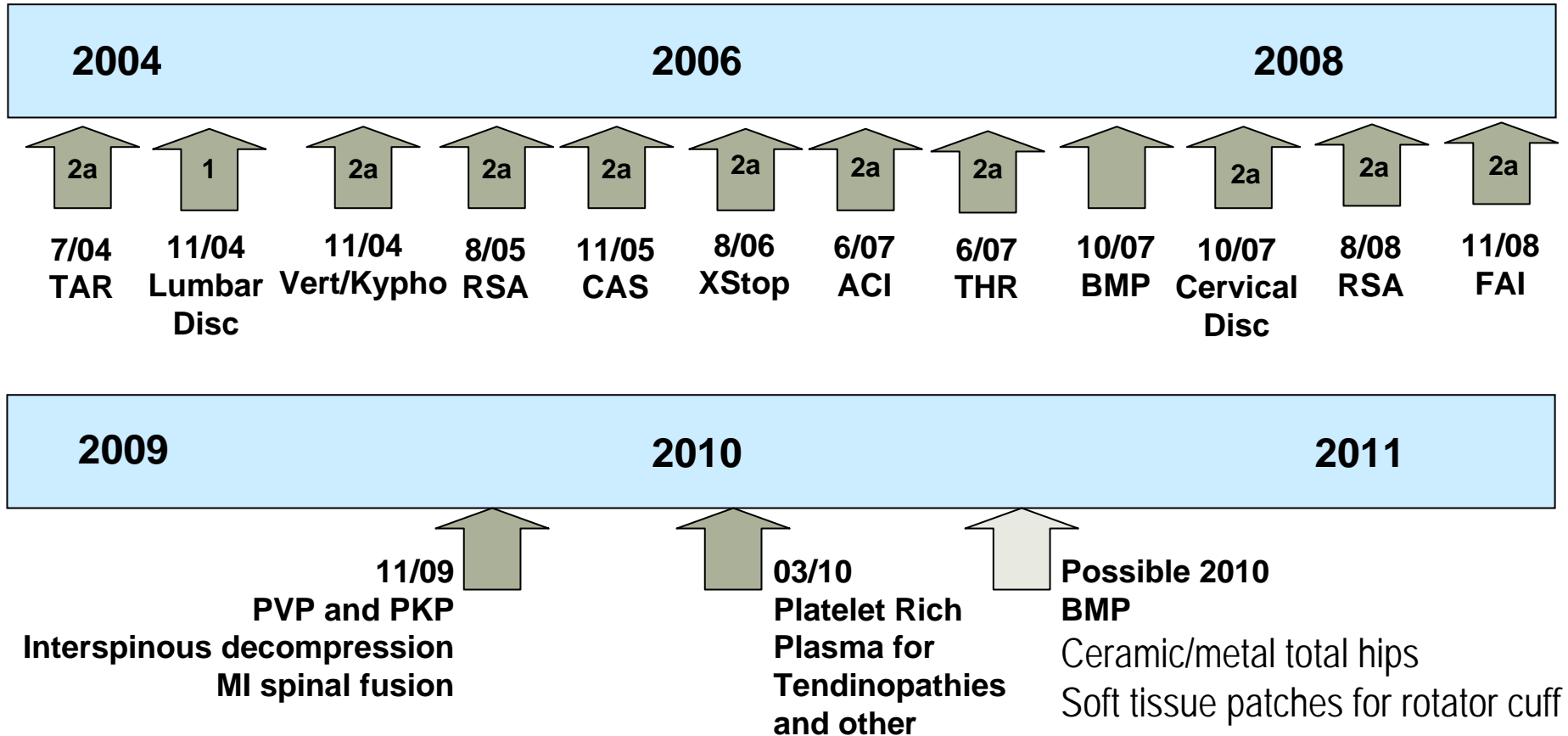
National Product Council  
(NPC)

Interregional Implant Registry  
Committee  
(IIRC)

# INTC Recommendations

1. Sufficient evidence  medically appropriate
2. Insufficient evidence:
  - a. no evidence
  - b. insufficient quantity and/or insufficient quality
  - c. conflicting or inconsistent
3. Sufficient evidence  not medically appropriate

# INTC Ortho Topics



1. Sufficient evidence (medically appropriate)

2b. Insufficient evidence (insufficient quantity and/or quality)



Search for  in [All Kaiser Clinical Content](#)

## [Clinical Guidelines](#) [\(View All\)](#)

[National Evidence-Based Guidelines](#)  
[Interregional Guidelines and Practice Resources](#)  
[Georgia Guidelines](#)  
[Group Health Cooperative Guidelines](#)  
[Ohio Guidelines](#)  
[New Clinical Technologies](#)  
[Clinical Resources by Topic](#)



## [Reference Shelf](#) [\(View All\)](#)

[Quick References](#)  
[KP Libraries and Online Catalog](#)  
[Search for Articles](#)  
[Nursing Resources](#)  
[Evidence-Based Resources](#)  
[Full-Text Books and Journals](#)  
[Calculators and Tools](#)  
[Clinical Trials and Research Initiatives](#)  
[Clinical Outcomes and Strategic Goals](#)

## [Clinician Education](#) [\(View All\)](#)

[Epic Learning Modules](#)  
[Nationally Sponsored CME Conferences](#)

## [Member Education](#) [\(View All\)](#)

[After Visit Summary Patient Instructions](#)  
[Drug Encyclopedia](#)  
[Health Encyclopedia](#)  
[Healthwise Handbook](#)  
[Ohio Health Education CORE Library](#)

## [Drug, Lab, Imaging](#) [\(View All\)](#)

[California DME Formulary](#)  
[Drug Facts and Comparisons](#)  
[Drug Formulary](#)  
[Micromedex](#)  
[National Pharmacy](#)  
[Natural Medicines Database](#)  
[Natural Standard](#)

## [Health Care News](#) [\(View All\)](#)

[KP News Center](#)  
[Yahoo Health News](#)

## [Operational Resources](#) [\(View All\)](#)

[Care Experience Council](#)  
[Care Management Institute](#)  
[InsideKP](#)  
[KP Community Benefit](#)  
[KP HealthConnect](#)  
[KP HealthConnect Community Library](#)

## National News

Tuesday, March 03, 2009

- **ImagesMD** will no longer be available through Clinical Library. Use of the site was minimal and the product was difficult to use. We apologize for any inconvenience. [Here are some alternatives.](#)
- [New Full Text Book and Journal List](#) Available on Jan 21.
- [DynaMed](#) is now available! DynaMed is a clinical reference tool, updated daily and contains over 3000 evidence based reviews.
- January 2009 [ABOG Board Certification Reading List](#), [November 2008 L3-ObGyn™](#) and the [2009 ABEM Life Long Learning & Self Assessment](#) have been posted
- CMI launches Pediatric and Bariatric components to their [Weight Management Initiative](#) Web site



[Home](#)[Members](#)[Assessments](#)[Minutes](#)[About](#)[Speaker Guidelines](#)[Subscribe](#)

## Next Interregional New Technologies Committee Meeting

- **March 2** - Oakland
- **June 1** - Los Angeles (Walnut Center in Pasadena)
- **Aug 31** - (teleconference, 10:00 am - 12:00 am PT)
- **Nov 16** - Oakland

[Download March 2 agenda](#)[Download Materials](#)

### Search

  Kaiser CMS FDA

### Contact Information

Medical Technology Assessment  
Inquiry Line:

- Northern California:  
(510) 987-3507
- All Other Regions:  
(626) 405-5138

### Subscribe to Newsletter

[Subscribe](#) to get notified when there is an update to a particular specialty or get INTC updates.

[Suggest a Topic](#)

### Minutes from Previous Meeting on November 17, 2008

- Proton Beam Therapy for Prostate Cancer
- Stereotactic Radiosurgery and Cyberknife
- High-intensity Focused Ultrasound (HIFU) for Prostate Cancer
- Stent Grafts for Endovascular Repair for Abdominal Aortic Aneurysm
- Stent Grafts for Endovascular Repair for Thoracic Aortic Aneurysm
- Applied Behavioral Analysis for Autism
- Femoroacetabular Surgery for Hip Impingement Syndrome
- Retained Foreign Object Prevention with Barcoding or RFID of Surgical Sponges

# Answering KP's Questions: Access and Pricing

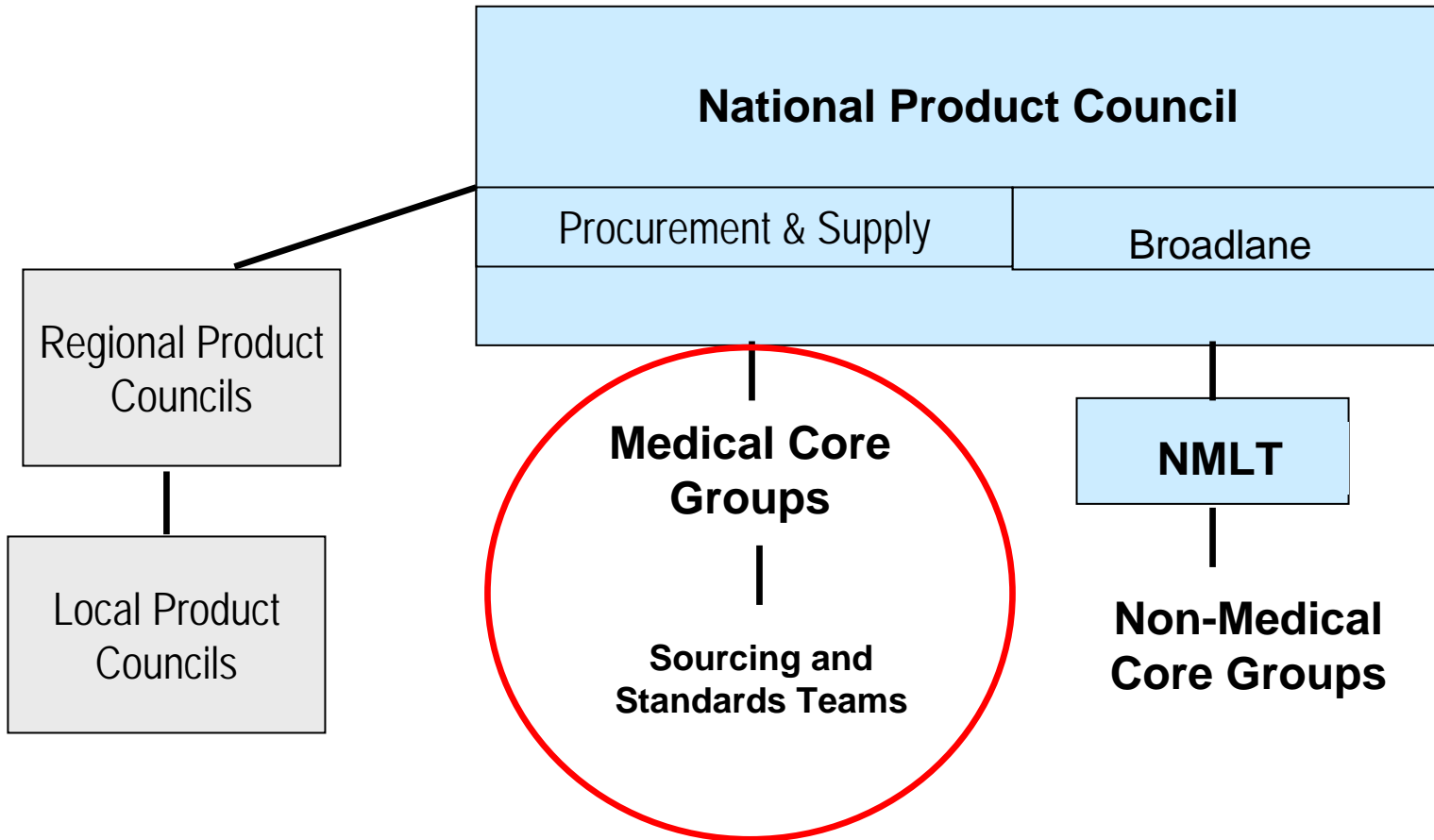
- Supports the delivery of quality health care... appropriate acquisition and utilization of high quality products
- incorporation of available evidence-based analyses, including technology assessments and clinical practice guidelines, into its product selection process.
- appropriate utilization through standardization
- selection and contracting based on quality, service, and total value

Interregional New Technologies  
Committee  
(INTC)

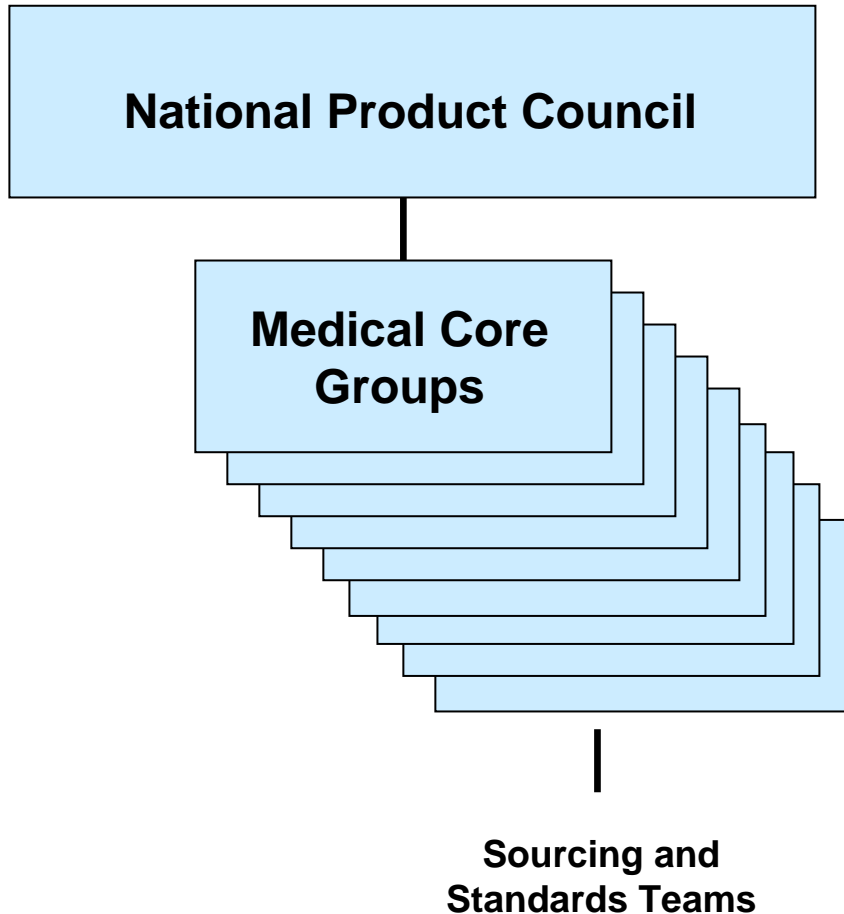
**National Product Council  
(NPC)**

Interregional Implant Registry  
Committee  
(IIRC)

# National Product Council

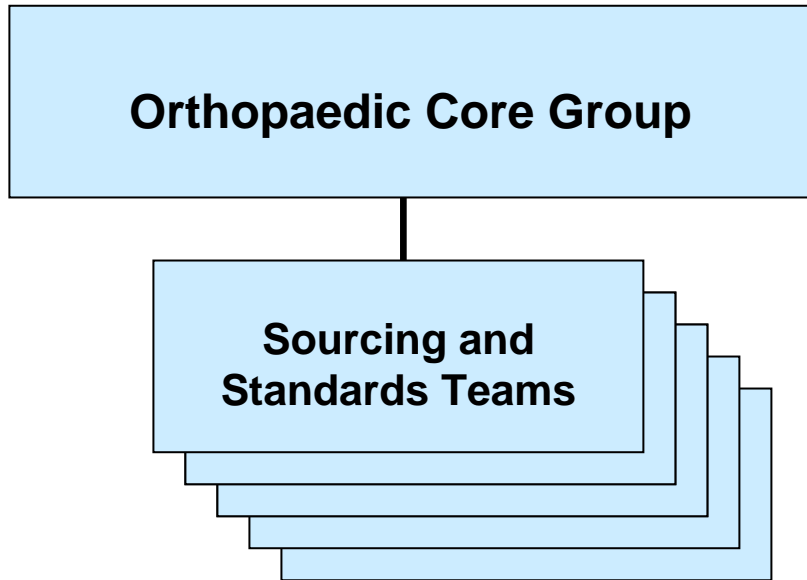


# National Product Council and the Core Groups



- Cardiology
- Imaging
- Lab – High Volume
- Lab – Medium Volume
- Medical
- Orthopaedics
- Physiological Monitoring
- Sharps
- Surgical

# The Orthopaedic Core Group and Teams



- Arthroscopy
- Joint Replacement
- Soft Goods
- Spine
- Trauma

# The Role of Core Group and Team Members

- Understand the FDA approval
- Seek existing data on the device
- Review with fellow surgeons
- Discuss with suppliers
- Determine classification as new product or new technology
- Determine pricing and other contractual considerations
- Educate peers and others
- Guide entry of products into KP facilities, if appropriate

# Defining New Technology vs. New Product

## Contractual Language: 2010 Joint Replacement Contract

- Defines new product vs new technology by FDA approval
- Guides pricing and introduction for new products
- Clarifies expectation for new technology
  - Published, peer-reviewed clinical data of sufficient quantity and quality that demonstrate clinically significant improvement in health outcomes or operational significant improvements

# 22 Devices Granted PMA through FDA in 2009

- [CONSERVE® Plus Total Resurfacing Hip System - P030042](#) Artificial Hip 11/03/09
- [VIDAS fPSA rt Assay - P080008](#) PSA Test 10/08/09
- [DuraSeal Spine Sealant System - P080013](#) Spine 09/04/09
- [Sculptra Aesthetic - P030050/S002](#) Wrinkles 07/28/09
- [TAXUS® Liberte™ Long \(2.75–4.00 mm x 38 mm\) Paclitaxel-Eluting Coronary Stent System \(Monorail and Over-the Wire Delivery Systems\) - P060008/S011](#) Stent 07/13/09
- [BRYAN® Cervical Disc - P060023](#) Cervical Disc 05/12/09
- [TAXUS® Liberté® Atom™ \(2.25 mm\) Paclitaxel-Eluting Coronary Stent System \(Monorail and Over-the Wire Delivery Systems\) - P060008/S008](#) Stent 05/21/09
- [REPEL-CV Bioresorbable Adhesion Barrier - P070005](#) Adhesion Barrier 03/06/09
- [ARCHITECT® CORE Reagent Kit, Calibrator and Controls - P080023](#) HBV Test 04/10/09
- [Medtronic® Attain Ability™ Model 4196 Lead - P080006](#) Pacemaker Leads 04/07/09
- [Cervista™ HPV 16/18 - P080015](#) HPV Test Kit 03/12/09
- [Cervista™ HPV HR and Genfind™ DNA Extraction Kit - P080014](#) HPV Test Kit 03/12/09
- [FC2 Female Condom - P080002](#) Condom 03/10/09
- [Synvisc-One \(hylan GF-20\) - P940015/S012](#) Osteoarthritis treatment 02/26/09
- [Reclaim™ DBS™ Therapy for OCD - H050003](#) Brain Stimulator 02/19/09
- [LifeStent FlexStar and FlexStar XL Vascular Stent - P070014](#) Stent 02/13/09
- [NAVISTAR® THERMOCOOL® and EZ Steer THERMOCOOL® Nav Irrigated Deflectable Diagnostic/Ablation Catheter for Treatment of Paroxysmal Atrial Fibrillation - P030031/S011](#) Catheter 02/06/09
- [XACT® Soft Acrylic UV Light-Absorbing Posterior Chamber Intraocular Lens - P080021](#) Intraocular Lens 02/02/09
- [TECNIS® Multifocal Foldable Silicone and Acrylic Intraocular Lenses - P080010](#)

## Approved by FDA through PMA in 2009: Ortho (4)

- CONSERVE® Plus Total Resurfacing Hip System - P030042 Artificial Hip 11/03/09
- DuraSeal Spine Sealant System - P080013 Spine 09/04/09
- BRYAN® Cervical Disc - P060023 Cervical Disc 05/12/09
- Synvisc-One (hylan GF-20) - P940015/S012 Osteoarthritis treatment 02/26/09

All the rest were HDE, 510(k) or supplemental approvals.

# Orthopaedic HUDs since 2004

- 07-Apr-2004 Stryker Biotech  
**OP-1 Putty**

For use as an alternative to autograft in compromised patients requiring revision posterolateral (intertransverse) lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected

- 24-Aug-2004 Synthes (USA)  
**Vertical Expandable Prosthetic Titanium Rib (VEPTR)**

For the treatment of Thoracic Insufficiency Syndrome (TIS) in skeletally immature patients. TIS is defined as the inability of the thorax to support normal respiration or lung growth. For the purpose of identifying potential TIS patients, the categories in which TIS patients fall are as follows: Flail Chest Syndrome  
Rib fusion and scoliosis  
Hypoplastic thorax syndrome, including Jeune's syndrome, Achondroplasia, Jarcho-Levin syndrome, Ellis van Creveld syndrome

- 10-Oct-2008 Medtronic Sofamor Danek.  
**INFUSE/MASTERGRAFT™ Posterolateral Revision Device**

Indicated for the repair of symptomatic, posterolateral lumbar spine pseudarthrosis. This device is intended to address a small subset of patients for whom autologous bone and/or bone marrow harvest are not feasible or are not expected to promote fusion. These patients are diabetics and smokers. This device is indicated to treat two or more levels of the lumbar spine.

# Answering KP's Questions: Product Effectiveness and Performance

- NPC sponsored & a formal National Quality Program
- Scope: implantable medical devices
- Advances knowledge about health outcomes associated with implants
- Applies data to benefit patients
- Supports quality improvement, patient safety initiatives & recalls
- Collaborates with INTC
- Provides product performance and utilization data to inform NPC
- Considers new registries
- Contributes to the knowledge of registries, internal and externally

Interregional New Technologies  
Committee  
(INTC)

National Product Council  
(NPC)

Interregional Implant Registry  
Committee  
(IIRC)

# Answering KP's Questions, Collectively

