

Clinical Development of Medical Devices

A Regulatory Perspective

Diaphragm Renaissance Workshop
September 10, 2002 (Seattle)

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Clinical Development of Medical Devices:
A Regulatory Perspective

- Device Classification
- Market Pathway
- Investigational Device Exemptions
- Other considerations

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Class I (General Controls)

- Registration & Listing
- 510(k) Premarket Notification
- Adulteration & Misbranding
- Design Controls for Manufacturing
- Repair, Refund, Return

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Class II (Special Controls)

- Performance Standards
- Postmarket surveillance
- Patient Registries
- FDA Guidelines
- Clinical Studies, if necessary

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Class III (Premarket Approval)

- ✓ Must submit a PMA application to FDA
- ✓ Must demonstrate safety & effectiveness
- ✓ With respect to:
 - target population
 - prescribed conditions of use (labeling)
 - benefit vs. risk

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Regulatory Pathways to Market

- 510(k) Premarket Notification

vs.

- Premarket Approval Application

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Regulatory Pathways to Market

510(k) Premarket Notification

substantial equivalence

in terms of safety & effectiveness

to a predicate device

with respect to intended use and design

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Regulatory Pathways to Market

510(k) Premarket Notification – practical points

90-day review cycle

Clinical studies, possibly

possible decisions

- ✓ AI ? answer FDA questions
- ✓ SE ? go to market
- ✓ NSE ? PMA

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Regulatory Pathways to Market

Premarket Approval Application

valid scientific evidence

safe (benefit outweighs risk)

effective (clinically significant result)

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Regulatory Pathways to Market

Premarket Approval Application – practical points

180-day review cycle

Clinical studies, almost certainly

Input from independent advisory panel

Pre-approval inspection of mfr facility

Careful labeling review

Postapproval studies (sometimes)

“Off-label” Use of Marketed Devices

- FDA’s “Practice of Medicine” Policy states that a physician should:
 - Be well informed about the product
 - Use firm scientific rationale and sound medical evidence
 - Maintain records on use and effects
- IDE not req’d; IRB/IC approval may be

Investigational Use

- Intend to study:
 - New intended use of approved device; or
 - New device
- Physician may be Investigator & Sponsor
- FDA approval of an IDE required?
 - Significant Risk -- yes
 - Nonsignificant Risk -- no

Significant Risk?

Presents a potential for serious risk to the health, safety, or welfare of the subject and may be:

- an implant
- life supporting/life sustaining; or
- of substantial importance in diagnosing, curing, mitigating, or treating disease.

Significant Risk -- Who Decides?

- Sponsor (S/I or firm) presents to IRB
 - IRB decides, consults, or defers
 - FDA - ultimate authority
- ⇒ If uncertain, use FDA's SR/NSR
Guidance and/or consult with IDE Staff

NSR versus SR

NSR

- IRB approval
- Informed Consent

SR

- IRB approval
- Informed Consent
- *FDA approval!!*

S/I vs Manufacturer IDE

S/I IDE:

- Usually pilot trials
- May reference other files
- Focus on safety
- Study design delayed until later

Manufacturer IDE:

- May have a pilot trial
- Complete IDE with mfg section
- Focus on safety and effectiveness

FDA will help you!!

- Informal Meetings
 - Pre-IDE
 - Pre-Pivotal
 - Pre-PMA
- Formal (FDAMA) Meetings
 - Determination
 - Agreement
 - Day 100 (after PMA submission)

Patient Protection Measures

- Informed Consent
- IRB approval
- Safety Data Monitoring Board

Other Considerations

- Differential protection vs. STDs:
Is this confusing to a patient?
- STD Study Methodology

Websites for Add'l Info

- 510(k) <http://www.fda.gov/cdrh/manual/510kprt1.html>
- IDE <http://www.fda.gov/cdrh/manual/idemanul.pdf>
- PMA <http://www.fda.gov/cdrh/manual/pmamanul.pdf>

Discussion Questions

What is a reasonable, achievable product claim, with respect to STD protection, for a diaphragm?

- Meaningful to patient
- Understandable, Not confusing
- Measurable

Discussion Questions

What are the key elements of a practical clinical study that would support such a claim?

- Study Population?
- Study Endpoints?
- Use Pattern?
- Time Frame for Patient Follow-up?
- How much difference is a 'clinically significant result'?