# US FDA Regulatory Paths and Considerations

## Ceramic & Antimicrobial Coatings

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# Regulatory-Path Options and Data Expectations

## Ceramic coated orthopaedic implants

- Special 510(k) using same product code / regulation
  - TiN coated version same as your 510(k)ed implant: design, indications, same implant system, same materials, instruments, surgical technique…*This is your primary predicate device*.
  - Implant with identical coating and product code was 510(k) cleared (*additional predicate*). Ideally can reference FDA Master File.
  - Minimal data requirements - Assumes adoption of prior work, i.e., packaging, ROM, constraint, instruments, cleaning, sterilization...
  - Assume biocomp basics, bioburden, cement adherence/fixation, porous coating strength/qualification, confirm engineering details.

TiN coated World Knee femoral component, Signature Orthopaedics

# Regulatory-Path Options and Data Expectations

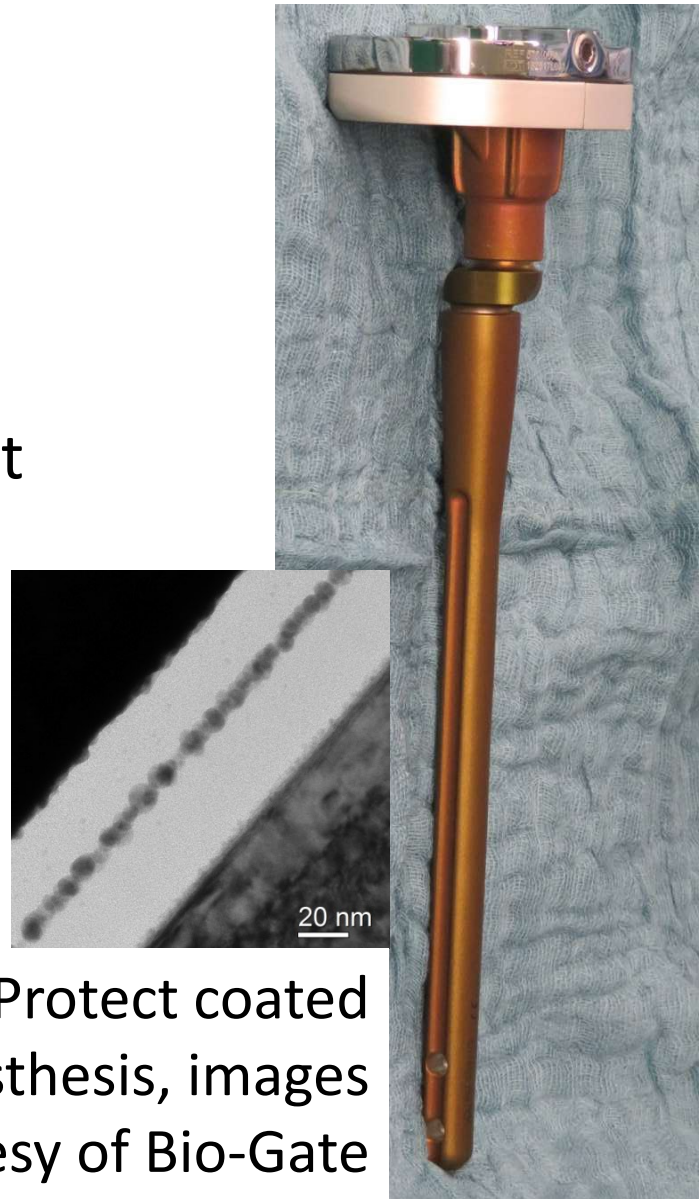
## Ceramic coated orthopaedic implants

- Traditional 510(k) if:
  - The coating is new to US market
    - Assumes coated implant will have clean predicate (same implant code/regulation)
  - The implant (with the coating) is new to US market
  - There is no predicate device with same coating on implant with same product code and same or similar indications for use
  - FDA data requirements typical of new device in same category + coating-specific data
    - For example, wear testing 5m cycles, pristine and abrasive conditions, ISO 10993-1 biocomp, constraint, ROM, contact mechanics, process V&V, etc. …
    - Coating hardness, properties, adhesion, scratch resistance, biocomp, abrasion...

# Regulatory-Path Options and Data Expectations

## Anti-microbial coated orthopaedic implants

- PMA or de novo request if coating chemistry / active ingredient (on a device) is new to US market and includes a "drug" component (e.g., gentamycin, vancomycin, silver…).
  - Device-led combination product…
- HUD / HDE route if technology is focused on specific patient population (up to 8000 patients/year in USA)
  - Stepping-stone, or end-goal of regulatory strategy…
- Traditional 510(k) if coating is comprised of existing biomaterials (with reference to implants that are 510(k)ed that have the coating)
  - Resorbable or non-resorbable




HyProtect coated prosthesis, images courtesy of Bio-Gate

# Anti-microbial considerations: de novo and PMA

First, consider submission for FDA's Breakthrough or STeP programs

- If: Technology is novel and pre-clinical data is supportive of potential success
- Because: FDA will provide more timely and interactive responses to future submissions and associated test plans and protocols

Strongly recommend pre-submission (Q-Sub) for PMA or de novo routes

- Because: ISO 10993-1, animal evidence, and clinical work are best negotiated and de-risked with FDA consensus upfront

Data requirements: Extensive, assume ISO 10993-1 to include E&L; coating tests to complete resorption, animal work to include equivalence of osteointegration, efficacy in animals, and likely level 1 RCT clinical study

# Anti-microbial considerations: 510(k)

Essentially same as de novo & PMA minus clinical requirement

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Strongly recommend pre-submission (Q-Sub) for PMA or de novo routes

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# Anti-microbial considerations: HDE / HUD

Upsides of HUD / HDE (up to 8000 cases in USA per year) include:

- Demonstration of clinical need / safety of device; Via prospective clinical study, document safety and efficacy for use in future marketing applications.
- Preparation of HUD akin to 510(k) in terms of providing FDA with documented evidence of safety (and potential efficacy).

Downsides of HUD / HDE include:

- Must justify to FDA the $ selling price for devices.
- Public disclosure of the HUD application and potential accessibility competition.
- Administratively burdensome requirements for maintaining approvals by FDA (annual reporting) and hospital ethics committees

# Summary

- Hard-coated implants with a predicate history: Recommend Special or Traditional 510(k) path; no-need for pre-submission.
  - Data requirements minimal or typical depending on 510(k) type
- Hard-coated implants & coating new to USA – recommend pre-submission
  - Data requirements typical PLUS performance and properties of coating
- Anti-microbial coatings with drug and no predicate: PMA or de novo with extensive pre-clinical and human data requirements.
  - Assume 4 to 6 years to US market (for clinical data)
  - HDE/HUD possible if fits company strategy; pre-clinical MAY be sufficient

# Thank You

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