KFDA Regulation for Combination Products

Medical Device Safety Bureau

KOREA FOOD & DRUG ADMINISTRATION

KFDA

“Combination Products”

- Therapeutic and diagnostic product that is comprised of two or more regulated component ; i.e.) drug/device, biologics/device combined as a single entity

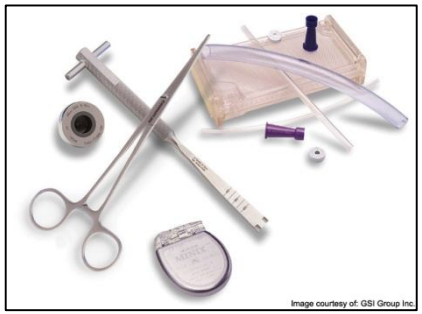
- Two or more separate products packaged together in a single package i.e.) drug/device, biologics/device

KFDA

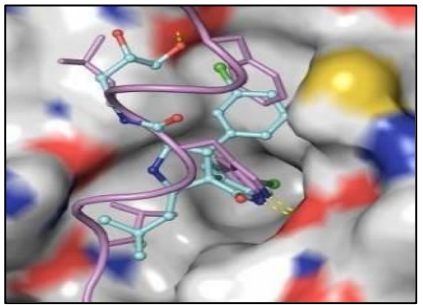
"I am a Combination Product"

Where Do I Go?

Drug



Device



Biologics

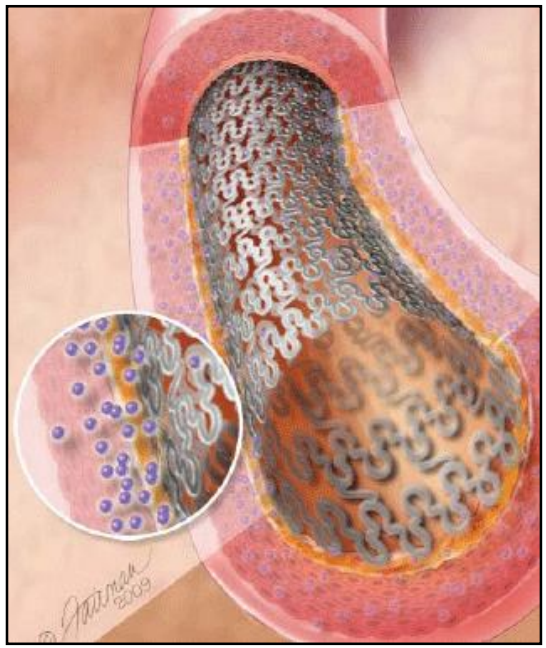
KFDA

“Primary Mode of Action”

The single mode of action of a combination product that provides the **most important therapeutic action** within the product.

- Most Important Therapeutic Action shows the greatest contribution in the **overall intended therapeutic effects** of a combination product.

“PMOA” DRUG or DEVICE ?

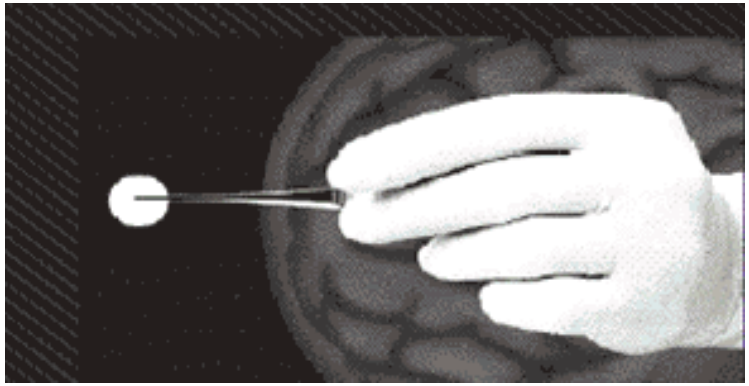


Drug Elution Stent

- Primary Mode of Action
  - Stent opens artery
- Secondary Action
  - Drug prevents inflammation & restenosis of artery

DEVICE

“PMOA” DRUG or DEVICE ?

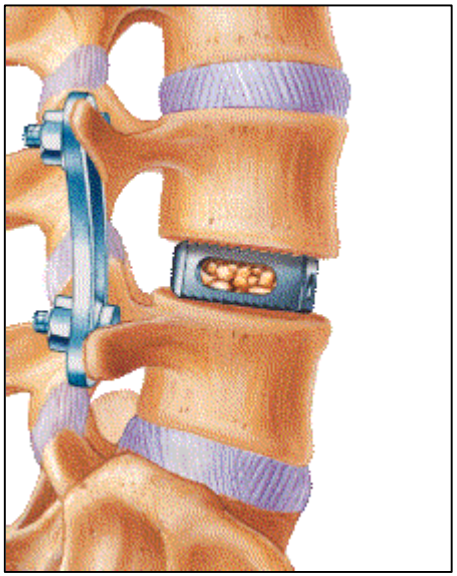


Drug Elution Disk

- Primary Mode of Action
  - Cancer chemotherapy for brain tumor
- Secondary Action
  - Local drug delivery of drug by device (degradable carrier)

DRUG

“PMOA” DEVICE or BIOLOGICS ?



Spinal fusion device coated with therapeutic protein to treat disc disease

- Primary Mode of Action
  - Mechanically maintain intervertebral spacing
- Secondary Action
  - Encourage formation of bone within fusion cage

DEVICE

“PMOA” DEVICE or BIOLOGICS ?

Interferon

Ribavirin

- Primary Mode of Action
  - Biologics to treat chronic hepatitis C (Interferon)
- Secondary Action
  - Drug improves liver function in hepatitis C patients (Ribavirin)

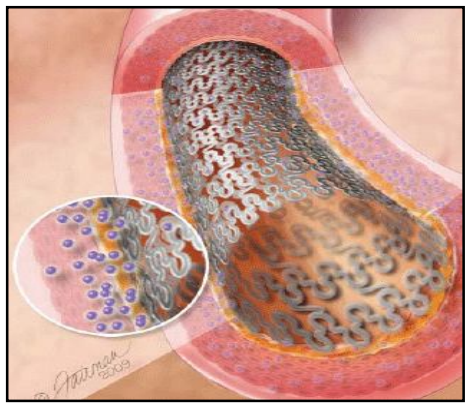
BIOLOGICS

KFDA

Approval process of C.P.

DES (Application for Approval) → CSO (Assign Lead Bureau) → MDSB (LEAD REVIEW) ↔ DSB (Drug review)

MDSB (LEAD REVIEW) → Approve as a MEDICAL DEVICE



Drug Elution Stent

Resolution Process of Disputes

1. Request for Designation(RFD)

2. Customer Support Officer(CSO) sends to the bureau concerned
   - If necessary,
   CSO may hold "Combination Product Classification Committee(CPCC)"

ChairPerson of CPCC
Director of Pharm. Safety Bureau

- Director of CSO and legal affairs office
- Director of Pharm. Safety Policy Div.
- Director of Biopharm. Policy Div.
- Director of Medical Device Policy Div.
- Director of Approval & Review management Div.
- Director of Cardiovascular Medical Device Div.
- Experts invited by the Chairperson

3. The director of the bureau concerned shall accept the decision of CSO or CPCC (RFD decision letter must issue within 30days)

THANK YOU


청사어린이집
| 식품의약품안전청 Vision |
종합시험실험동
국립독성연구원
식품의약품안전청
중앙통제센터
질병관리본부
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