APEC-AHC-AHWP Joint Workshop on Medical Device Combination Products

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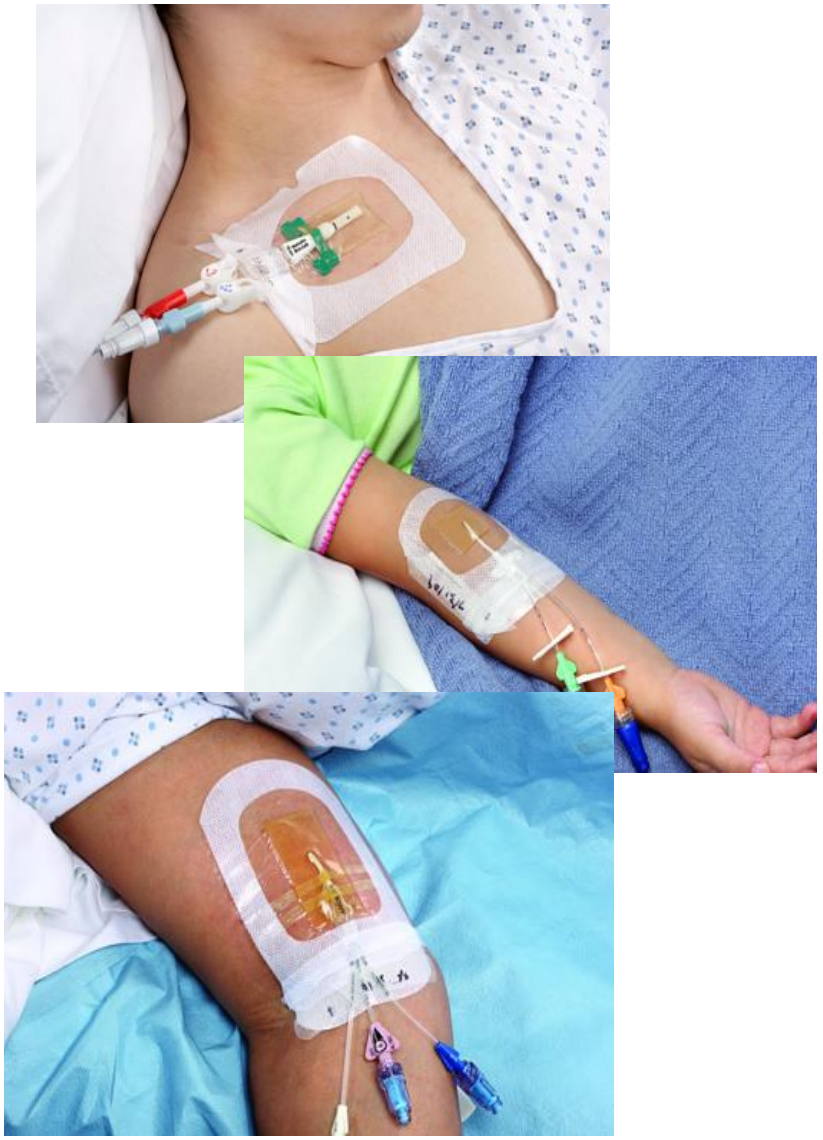
3M

Case Study Outline

1. Product Overview
2. Primary Mode of Action (PMOA) and Classification
3. US Filing Strategy
4. Quality System Requirements

3M™ Tegaderm™ CHG Securement Dressings?

- Intended Use: 3M™ Tegaderm™ CHG Dressing, Chlorhexidine Gluconate I.V. Securement Dressing, can be used to cover and protect catheter sites and to secure devices to skin. Common applications include securing and covering IV catheters, other intravascular catheters and percutaneous devices.

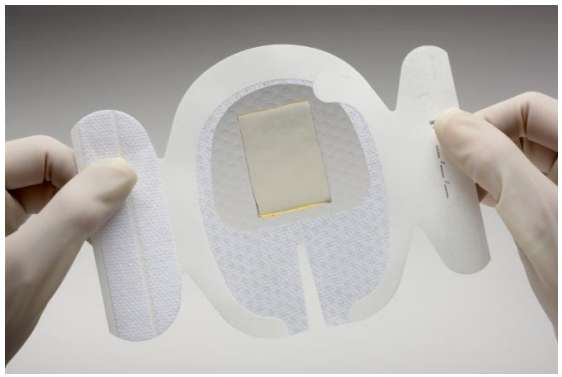


Why we developed Tegaderm™ CHG dressings?

- Clinicians Asked for an Antimicrobial Dressing That …
- Contains CHG a well studied antimicrobial
  - Controls skin flora
  - Effective immediately
- Transparent to monitor insertion site daily for complications
- Has the potential to reduce nursing time and save money - integrated design

Tegaderm™ CHG Dressing

- Gel pad integrated with existing Tegaderm™ transparent film dressing
  - Transparent
  - Able to absorb fluids
  - Conformable



- 2% CHG availability
  - Well known and accepted antiseptic
  - Does not require additional skin moisture for antimicrobial effect
  - Skin flora reduction demonstrates consistent availability up to 10 days
  - CHG migrates to areas not in direct contact with gel

Consideration s in the Design and Strategy

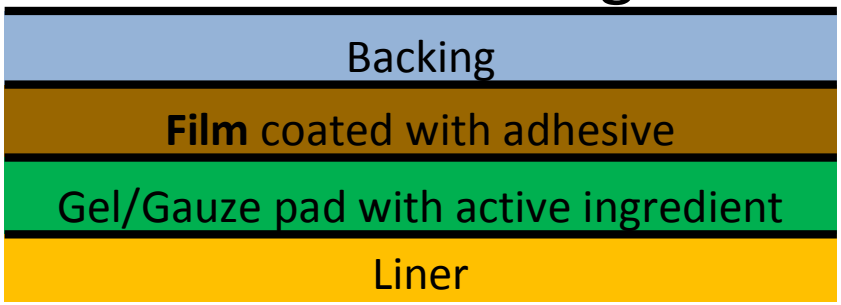
- Incorporate two existing 3M competencies
  - CHG Antiseptics
  - Flat film wound dressings
- Use USP and BP grade CHG to minimize active ingredient questions
- Have a well established predicate for the US filing
- Eliminate need for clinical studies by using existing data from published sources

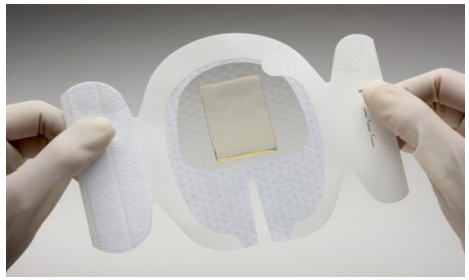
WHAT IS THE REGULATORY CLASSIFICATION AND PRIMARY MODE OF ACTION?

HOW WILL IT BE REGULATED - DEVICE OR DRUG?

Technology: Combination Wound Dressing Typical Constructions

Pad with Drug



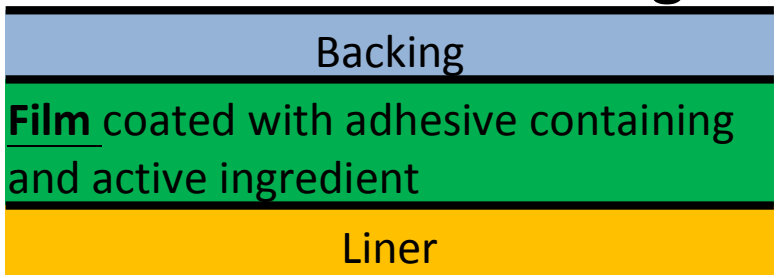


Device

Wound dressings

- Protects IV site or wound
- Absorb fluid
- Localized effect of drug
- 21 CFR 820 Quality System Regulations

Adhesive with Drug



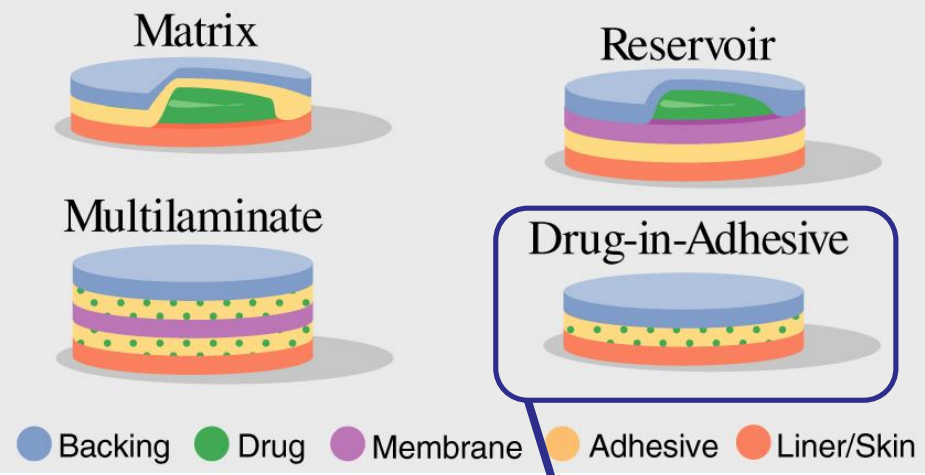
Primary Mode of Action – Physical

Protect Site and Securement of Catheter

- The primary mode of action for Tegaderm™ CHG dressing is a dressing used to secure devices to skin;
- The secondary mode of action is to provide antimicrobial activity in the dressing and to broad spectrum antimicrobial and antifungal activity at the IV site.

Drug Delivery Patches

Technology and Primary Mode of Action



Drug Delivery Patches

- Primary mode of action Chemical - Regulated as a pharmaceutical
  - Provides controlled release of drug for various treatments
- Adhesion ensures drug delivery efficiency and can be customized for duration of wear

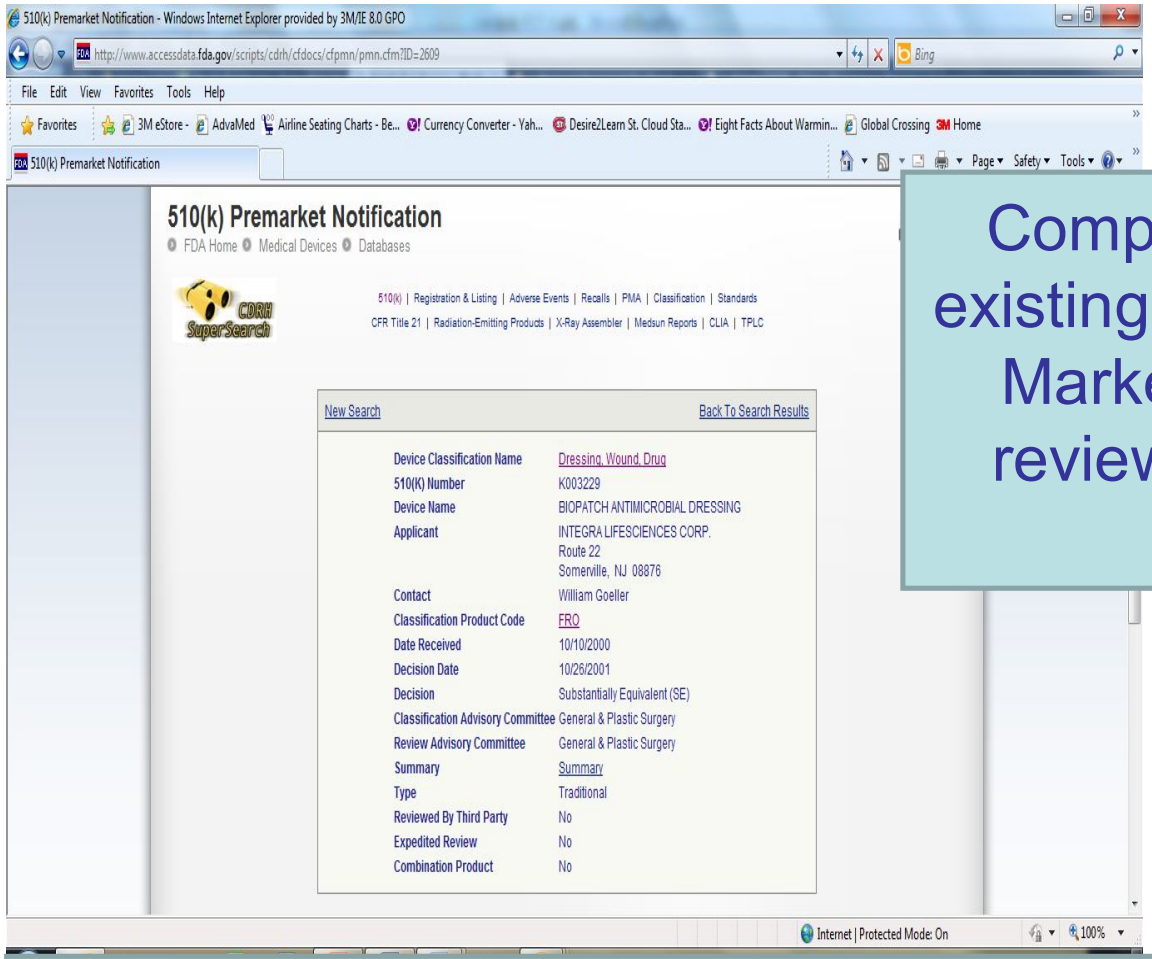
CONSTRUCTION and TECHNOLOGY of Drug Deliver patch similar to wound dressing products, but the intended use is and primary mode of action is VERY different. Therefore wound dressings are regulated as Medical Devices

Based on PMOA Determined Global Regulatory Classification

Tegaderm ™ CHG dressing is sold globally and approved in over 40 countries as a medical device

Country	Classification
US	(FRO) Unclassified – 510K route
EU	III
Australia	III
Japan	III
GHTF	Class D

How Did We Confirm US Classification?

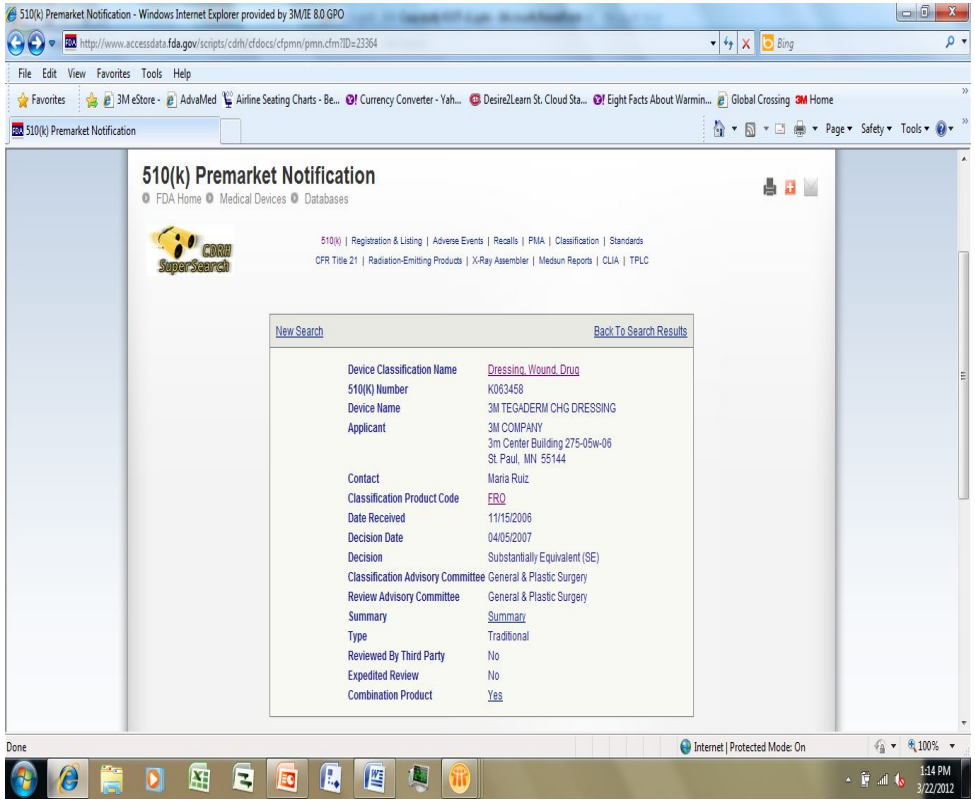


Compared our product to existing products on the U.S. Market (Predicates) and reviewed their regulatory status

Additionally, we consulted with US FDA Office of Combination products to verify our understanding early in the development process

US Regulatory Submission

- 3M filed the required 510K in Nov 2006
  - Standard 510K data was submitted
    - Substantial Equivalence to predicate
    - Safety ISO 10993 testing
    - No clinical study was required
  - Received clearance in April 2007



Quality System Requirements

- Production was established in our existing wound dressing manufacturing facilities under a 21 CFR 820 compliant Quality Management System
- Using a risk management approach, increased controls have been implemented within our medical device site based on US FDA guidance

Conclusions

- Regulatory path was determined by primary mode of action
- Clear processes to obtain requirements and classification existed
- Existing quality system framework could be amended to meet added “risk” of combination products in production

THANK YOU

QUESTIONS?