Moving From the Lab to the Market

5 Key Factors to Help Bridge the Gap

Lauren Baker, PhD
Senior Clinical/Regulatory Advisor, Sunrise Labs

2021

My Background

WPI

Clinical Research

UMassMemorial Medical Center

Boston Scientific

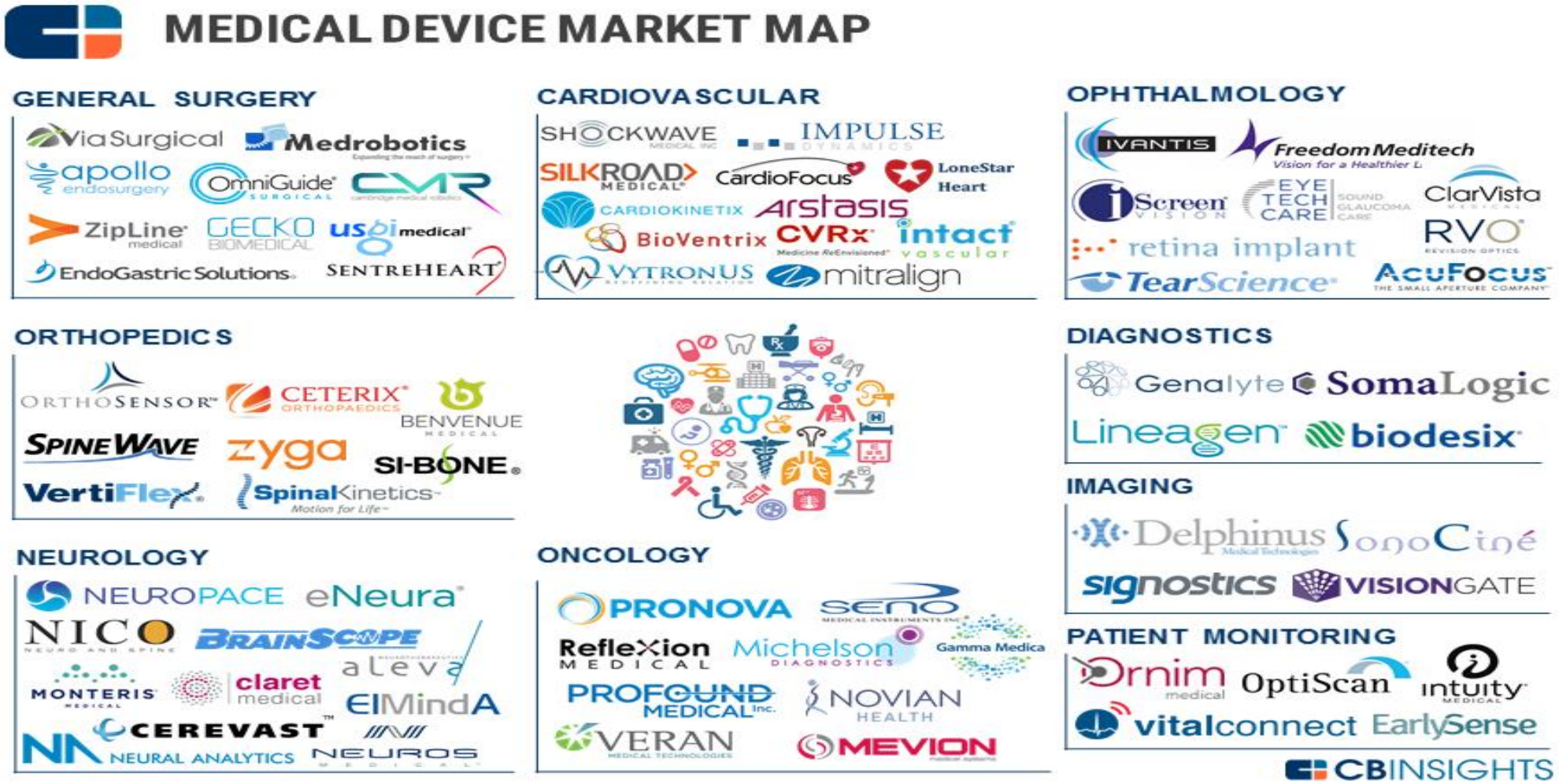
Regulatory Affairs

BBA
BOSTON BIOMEDICAL ASSOCIATES

Entrepreneur with successful Business Sales

SUNRISE LABS

Medical Arena NOW —MORE than just a *WIDGET* and FAST-Changing….



SUNRISE LABS

The Gap

The Key Factors:

- The (right) BIG Idea
- The Funding maze
- Your TEAM
- Your Partners - Investors, FDA, Payors
- Developing the Playbook
- Executing EFFICIENTLY
- Making the BIG Idea a reality

SUNRISE LABS

The BIG Idea – More than just a cool widget?

Identify the NEED

- Select the Clinical Area of Medicine
- Observe!
- What is the underlying problem?
- Develop the NEED STATEMENT

Identify the Business Realities

- Brainstorm solutions
- In depth business analysis
- Talk to the STAKEHOLDERS

ESTABLISH THE BIG IDEA

SUNRISE LABS

The NEED Statement – EXAMPLE

NEED to reduce catheter related bloodstream infections

- *NOT*, a new catheter coating to reduce infection

NEED to reduce incidence of diabetic ketoacidosis

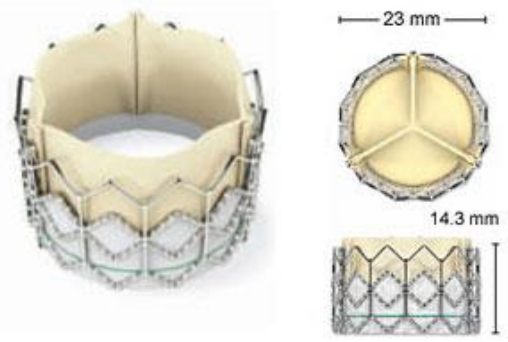
- *NOT*, a new continuous glucose monitoring catheter

SUNRISE LABS

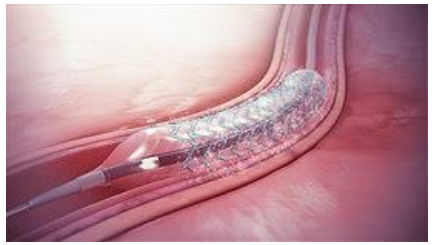
Understand the Value Proposition of the BIG IDEA

Reward

New paradigm



Platform



Niche Products

Risk

SUNRISE LABS

The Funding MAZE – Finding the (right) Investor

- SEED, Angel, Friends and Family
- Venture Capital
- Strategic Partners
- Initial Public Offering (IPO)

Align the funder with the development stage!

SUNRISE LABS

Business Analysis → The TEAM

- Financing
- Cost of Goods
- Pricing
- Competitive Dynamics
- Regulatory Strategy
- Exit Strategy

→

- Investors
- Development Partners
- Payors
- Market Research
- Understand the FDA Reviewers
- Stay in touch with strategics/bankers

SUNRISE LABS

The Balance

Targeted Marketing Plan

Strong Regulatory Strategy

Financial Support

Successful and Timely Product Introduction

SUNRISE LABS

Developing THE Plan

- Market approval regulations – regional based
- Timing to market launch
- Vigilance requirements
- Standard reporting requirements

SUNRISE LABS

Pre-Market Regulatory Plan – 4 Steps

1. Determine product categorization
   - Drug, Device, Biologic or Combination
2. Determine type of submission
   - US: PMA vs 510(k) vs BLA vs NDA
3. Develop appropriate strategy
   - Pre-submissions?
   - Pre-meetings with regulators?
4. Consider reimbursement

SUNRISE LABS

STEP 1: Product Categorization

Medical Device, Drug, Biologic or combo

Key is to assess:

- Primary Mode of Action (PMOA)
- Claims

Examples:

- Drug Coated Stent: PMOA is mechanical
- Bone Morphogenic Protein: PMOA is mechanical
- SoloSTAR Pen: PMOA is medicinal

SUNRISE LABS

STEP 2: Determine Appropriate Regulation

PMA or 510(k)?

Review FDA guidance documents

FDA database search for similar products

- www.fda.gov

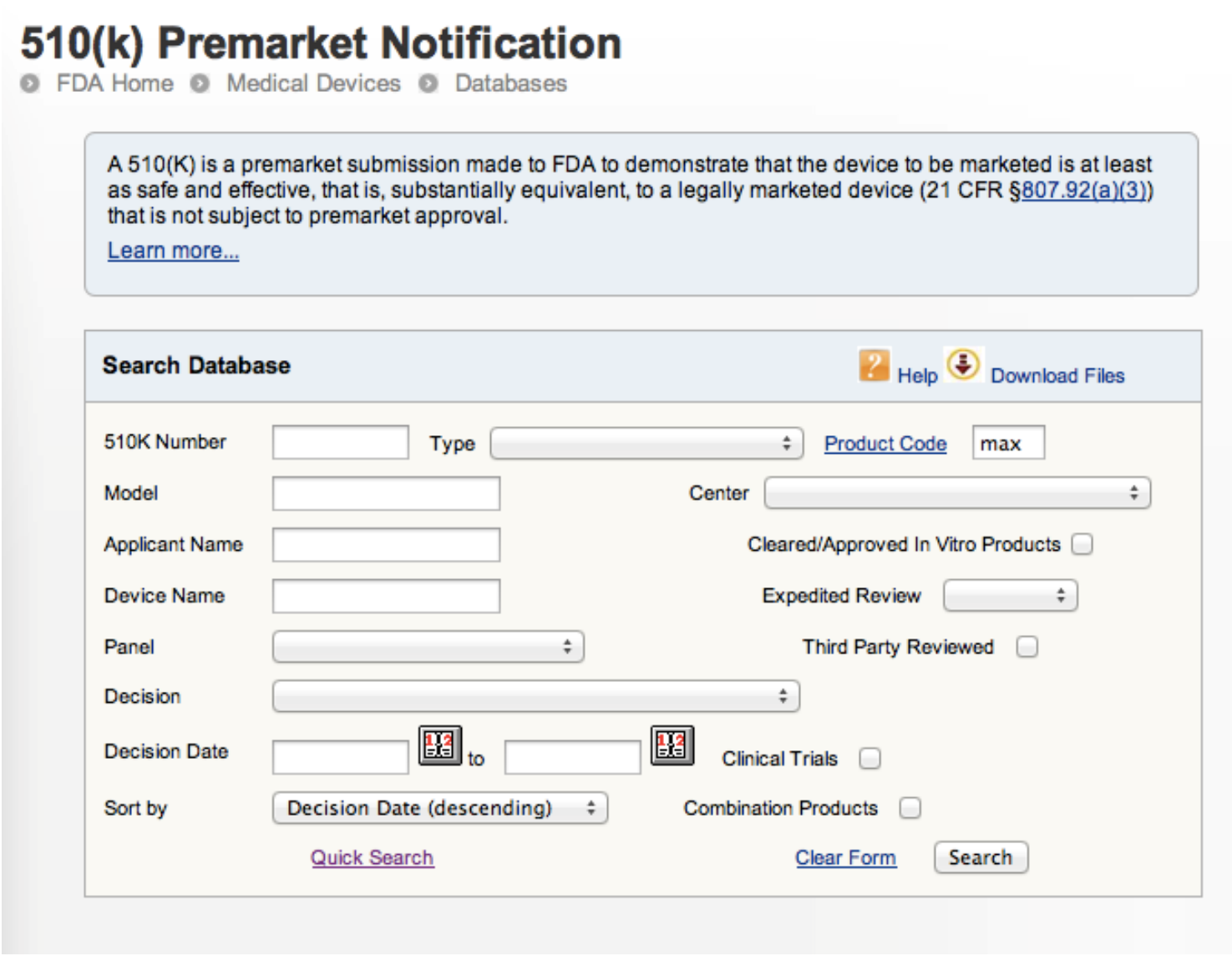
Utilize PRO CODES and Regulations

Review relevant 510(k) Summaries and PMA SSEDs (Summary of Safety And Effectiveness) for insight

SUNRISE LABS

The 510(k) Database

www.fda.gov



SUNRISE LABS

Search Results

510(k) Premarket Notification

FDA Home › Medical Devices › Databases

1 to 10 of 314 Results
ProductCode: *max* **Decision Date To:** *02/16/2014*

1 2 3 4 5 6 7 8 9 10 >

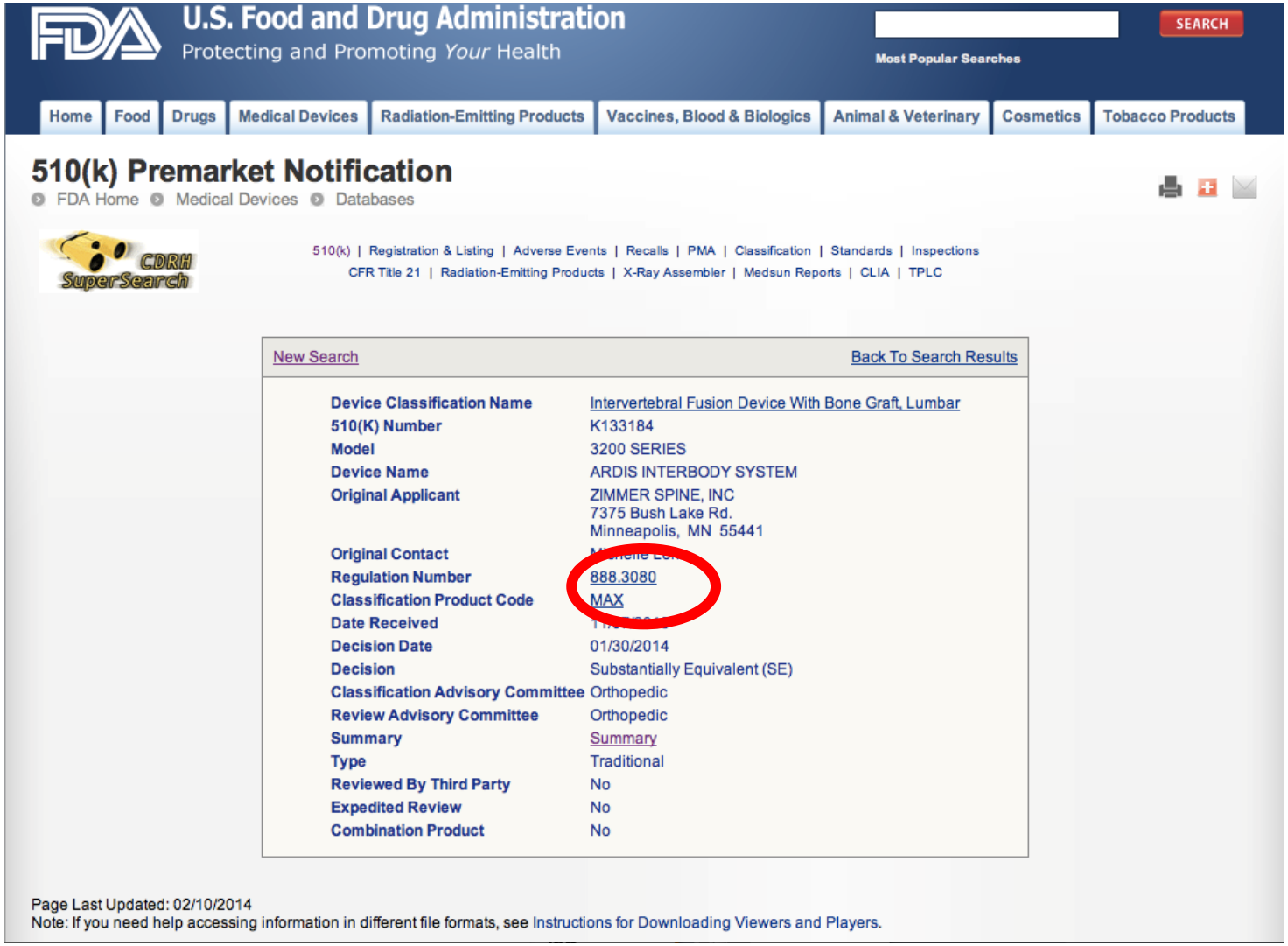
Results per Page 10

New Search | Export to Excel | Download Files | More About 510(k)

Device Name	Applicant	510(K) Number	Decision Date
Deroyal Spine Spacer System	Deroyal Industries, Inc.	K131292	02/03/2014
Juliet LI Lateral Lumbar Cage	Spineart	K133557	02/03/2014
Interbody Cage System	Aurora Spine	K133967	01/31/2014
Ardis Interbody System	Zimmer Spine, Inc	K133184	01/30/2014
Mectalif Tipeek	Medacta International	K133192	01/30/2014
Aesculap Peek Xp Spinal Implant System	Aesculap Implant Systems, Inc.	K132421	01/22/2014
Tasmin R	Signus Medizintechnik Gmbh	K123758	01/14/2014
Rampart-L	Spineology, Inc.	K133371	01/09/2014
Perimeter C Spinal System, Capstone Spin	Medtronic Sofamor Danek Usa, Inc.	K133645	01/03/2014
Coroent Sterile Implants System	Nuvasive, Incorporated	K132601	12/24/2013

SUNRISE LABS

Specific Example



U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

SEARCH

Most Popular Searches

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

510(k) Premarket Notification

FDA Home › Medical Devices › Databases

CDRH SuperSearch

510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards | Inspections
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search — Back To Search Results

Device Classification Name	Intervertebral Fusion Device With Bone Graft, Lumbar
510(K) Number	K133184
Model	3200 SERIES
Device Name	ARDIS INTERBODY SYSTEM
Original Applicant	ZIMMER SPINE, INC 7375 Bush Lake Rd. Minneapolis, MN 55441
Original Contact	[redacted]
Regulation Number	888.3080
Classification Product Code	MAX
Date Received	[redacted]
Decision Date	01/30/2014
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No
Combination Product	No

Page Last Updated: 02/10/2014
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

SUNRISE LABS

The “regulation”

PART 888 -- ORTHOPEDIC DEVICES

Subpart D--Prosthetic Devices

Sec. 888.3080 Intervertebral body fusion device.

(a) *Identification* . An intervertebral body fusion device is an implanted single or multiple component spinal device made from a variety of materials, including titanium and polymers. The device is inserted into the intervertebral body space of the cervical or lumbosacral spine, and is intended for intervertebral body fusion.

(b) *Classification* . (1) Class II (special controls) for intervertebral body fusion devices that contain bone grafting material. The special control is the FDA guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device." See 888.1(e) for the availability of this guidance document.

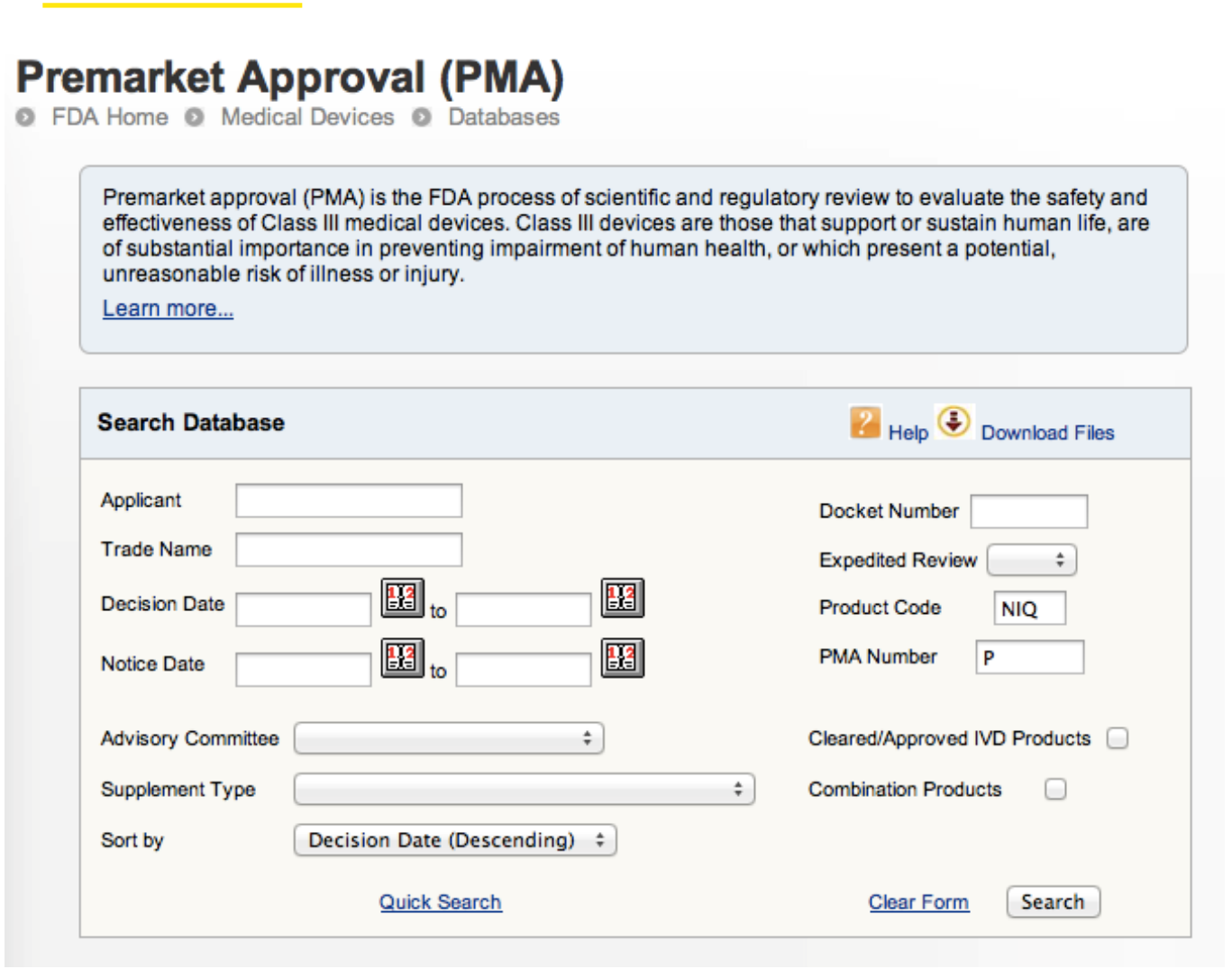
(2) Class III (premarket approval) for intervertebral body fusion devices that include any therapeutic biologic (e.g., bone morphogenic protein). Intervertebral body fusion devices that contain any therapeutic biologic require premarket approval.

(c) *Date premarket approval application (PMA) or notice of product development protocol (PDP) is required.* Devices described in paragraph (b)(2) of this section shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[72 FR 32172, June 12, 2007]

SUNRISE LABS

The PMA Database



SUNRISE LABS

Search Results

Premarket Approval (PMA)

FDA Home › Medical Devices › Databases

1 to 10 of 500 Results *
Product Code: *NIQ* **Decision Date to** *02/16/2014*

1 2 3 4 5 6 7 8 9 10 >

Records per Page 10

New Search | Export to Excel | Download Files | More About PMA

Device Name	Applicant	PMA Number	Decision Date
ION PACLITAXEL-ELUTING PLATINUM CHROMIUM	Boston Scientific	P100023 S083	02/06/2014
ION PACLITAXEL-ELUTING CORONARY STENT SY	Boston Scientific	P100023 S085	02/06/2014
PROMUS ELEMENT PLUS/PROMUS PREMIER EVERO	Boston Scientific	P110010 S066	02/06/2014
RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING C	Medtronic Ireland	P110013 S007	02/05/2014
RESOLUTE INTEGRITY RX ZOTAROLIMUS ELUTIN	Medtronic Ireland	P110013 S024	02/05/2014
ENDEAVOR SPRINT ZOTAROLIMUS ELUTING CORO	Medtronic Vascular	P060033 S086	02/03/2014
RESOLUTE INTEGRITY ZOTAROLIMUS ELUTING C	Medtronic Vascular	P110013 S033	02/03/2014
RESOLUTE INTEGRITY ZOTAROLIMUS ELUTING C	Medtronic Vascular	P110013 S028	01/30/2014
TAXUS LIBERTE PACLITAXEL-ELUTING CORONAR	Boston Scientific	P060008 S107	01/21/2014
ENDEAVOR SPRINT ZOTAROLIMUS-ELUTING CORO	Medtronic Vascular	P060033 S085	01/14/2014

* The maximium 500 devices meeting your search criteria returned. Please narrow your search.

SUNRISE LABS

The Example

New Search | Back to Search Results

Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the original PMA to get an up-to-date view of this device.

Trade Name	TAXUS LIBERTE PACLITAXEL-ELUTING CORONARY STENT SYSTEM
Classification Name	Coronary Drug-Eluting Stent
Applicant	BOSTON SCIENTIFIC
PMA Number	P060008
Supplement Number	S107
Date Received	10/25/2013
Decision Date	01/21/2014
Product Code	NIQ [Registered Establishments With NIQ]
Advisory Committee	Cardiovascular
Supplement Type	Normal 180 Day Track No User Fee
Supplement Reason	Postapproval Protocol Or Modification To A Protocol
Expedited Review Granted?	No
Combination Product	No

Approval Order Statement
Approval of the post-approval study protocol.

SUNRISE LABS

The SSED

Summary of Safety and Effectiveness Data

GENERAL INFORMATION

Product Generic Name:	Drug-Eluting Coronary Stent System (NIQ)
Product Trade Name:	TAXUS® Liberté® Paclitaxel-Eluting Coronary Stent System (Monorail) TAXUS® Liberté® Paclitaxel-Eluting Coronary Stent System (Over-the-Wire)
Applicant's Name and Address:	Boston Scientific Corporation One Boston Scientific Place Natick, MA 01760-1537 USA
Premarket Approval Application (PMA) Number:	P060008
Date of Panel:	None
Date of Notice of Approval to	October 10, 2008

STEP 3: Determine Specific Regulatory Requirements

Review FDA guidance documents

- Example: “Coronary Drug-Eluting Stents – Nonclinical and Clinical Studies”

Review relevant SSED’s for insight

- Example: SSED for Taxus DES

Couple the research with engineering expertise to develop a plan

SUNRISE LABS

FDA Discussions – When?

Outstanding questions that are costly

- Which animal model?
- How many animals are appropriate?

Novel clinical study design

- Adaptive trial design
- Objective Performance Criteria vs. RCT

Challenge to a regulatory pathway

- Regarding product as a 510(k) vs PMA

SUNRISE LABS

FDA Discussions – How?

Contact review division chair

- Will likely connect you to a reviewer or project manager

Prepare a formal Pre-Submission

- Written document including:
  - Product description
  - Proposed indication
  - Proposed test plan and protocol summary
  - Specific questions requiring FDA input

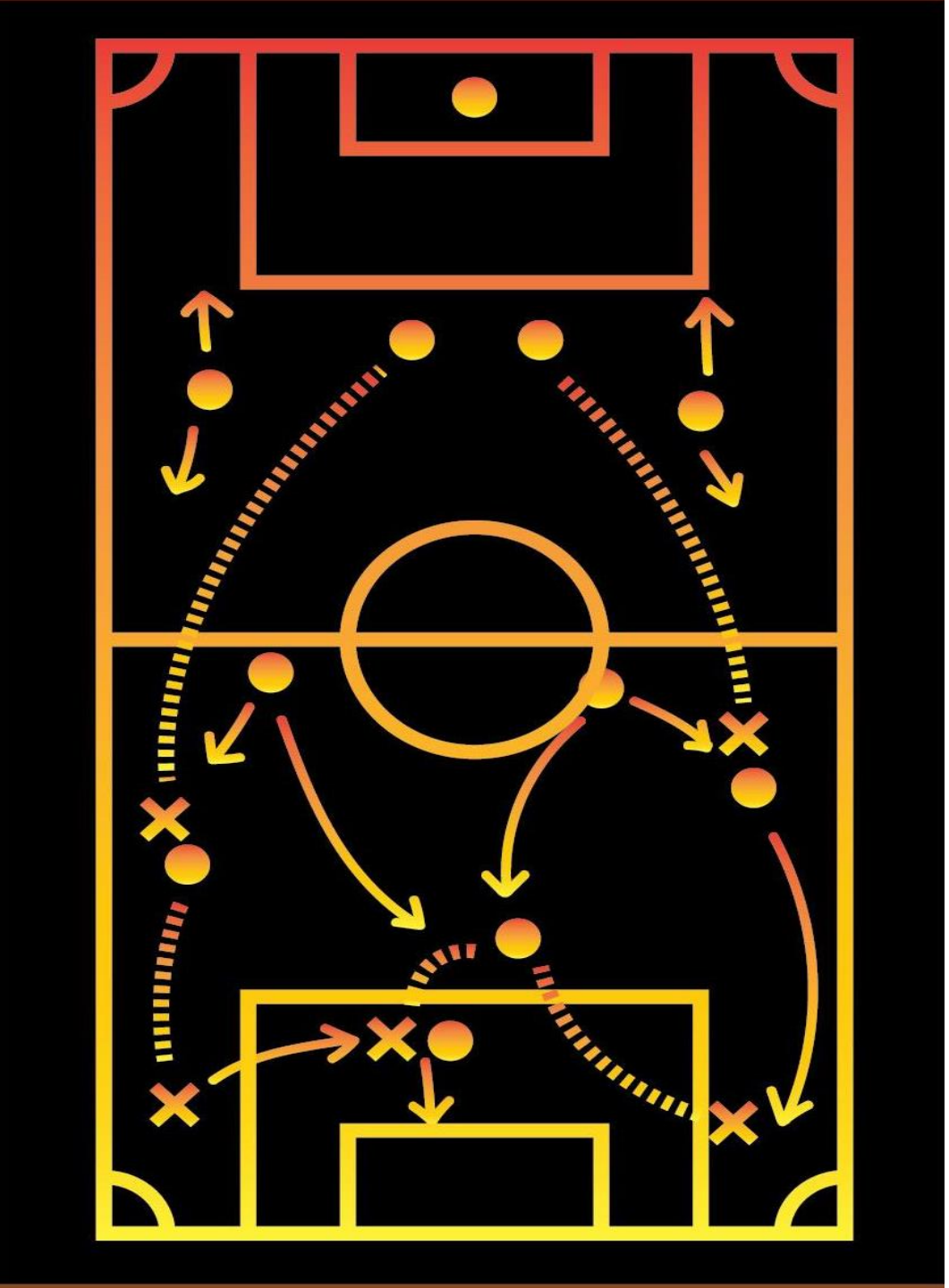
SUNRISE LABS

STEP 4: Reimbursement

A Complicated and Ever-Changing Labyrinth

- Location of administration of product – in hospital/out of hospital/home
- Who administers – physician/nurse
- Existing DRG code?
- Novel/Breakthrough?

SUNRISE LABS



Summary – Producing your Playbook

- Understand your technology and **THE NEED**
- Do your homework on approval options
- Determine where the product fits in the reimbursement structure
- Set Up your TEAM and Develop the Playbook

SUNRISE LABS

Closing the GAP

- THE NEED
- A Product
- THE Plan
- Documentation!
- TEAM

SUNRISE LABS

Questions?

SUNRISE LABS

Thank you!

Every Great Project Starts With A Thoughtful Conversation

Contact Us

Barbara Gibney

Director of Marketing

bgibney@sunriselabs.com

Sunrise Labs