

Regulatory Strategy Forum for Medical Devices

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Inmotion Musculoskeletal Institute

Role of Regulatory Intelligence in Regulatory Strategy Development

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Context

- The global regulatory environment is getting increasingly complex
- Evaluating all relevant sources of information that could impact your regulatory strategy has never been more important
- The good news: obtaining regulatory intelligence has never been easier



What is Regulatory Intelligence?

Regulatory Intelligence includes:

- gathering and analyzing publicly available regulatory information
- communicating the implications of that information
- monitoring the current regulatory environment
- looking for opportunities to shape future regulations, guidance, policy, and legislation

Ref: Regulatory Intelligence Network Group, DIA RA SIAC



Role of Regulatory Intelligence

- Regulatory intelligence helps build device development strategies by examining:
 - Regulatory precedent
 - Regulatory pathways for competitor products
 - Data requirements
 - Competitor's labeling and promotion
 - Competitor's adverse events and recalls
 - Company Press Releases
 - Registration procedures & approval trends
 - Review division/Reviewer profiles

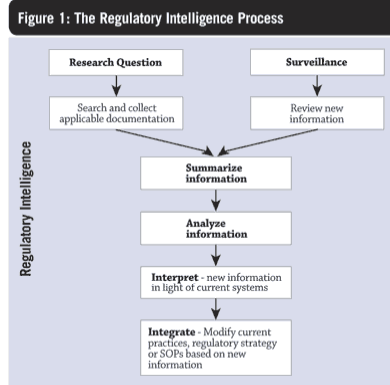


Regulatory Intelligence Tools

- Health Authority websites
- Regulatory Intelligence Databases
- Regulatory Alerts/Updates
- Industry/Professional Association websites
- Professional journals
- Newsletters
- Business Intelligence Services
- Discussion Groups/Forums/Blogs
- Consultants
- Colleagues



The Regulatory Intelligence Process



Health Authority Websites - FDA

The screenshot shows the FDA website homepage. Several elements are circled in blue:

- The left navigation menu, including categories like Food, Drugs, Medical Devices, Biologicals, Blood & Vaccines, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Combination Products.
- The "Science & Research" section, which includes links for Modernizing the Critical Path Sciences, Clinical Trials, Pediatric Therapeutics, Rare Diseases, and Toxicological Research.
- The "Regulations & Laws" section, featuring links for commenting on proposed regulations, Code of Federal Regulations, Dockets, Federal Register, and Laws FDA Enforces.
- The "About FDA" section, containing information about the FDA Organization, Advisory Committees, International Programs, FDA's Strategic Plan, Budget, Career Opportunities, and Manuals and Publications.
- The "In The Spotlight" section, which highlights key initiatives and news items.
- The "News & Events" section, providing updates on FDA activities and approvals.
- The "FDA For You" section, offering resources for Consumers and Industry.
- The "A-Z Index" and "Most Popular" sections on the right side of the page.

The URL www.fda.gov is displayed in the top right corner. The RAPS.org logo is visible in the bottom right corner.

Search Information

The screenshot displays the FDA 510(k) Database search interface. At the top, a navigation bar includes links for 510(k), Registration & Listing, Adverse Events, Recalls, PMA, Classification, Standards, CFR Title 21, Radiation-Emitting Products, X-Ray Assembler, Medsun Reports, and CLIA. The search form includes the following fields and options:

- Search 510(k) Database** (with links for Download Files and More About 510(k))
- 510K Number**: Input field with "K" and a dropdown for **Type**.
- Model**: Input field.
- Applicant Name**: Input field.
- Device Name**: Input field.
- Panel**: Dropdown menu.
- Decision**: Input field.
- Decision Date**: Range selection from [start] to [end] with calendar icons.
- Sort by**: Dropdown menu set to "Decision Date (descending)".
- Additional filters**: Checkboxes for Cleared/Approved IVD Products, Expedited Review, Third Party Reviewed, and Product Code.
- Search options**: Search, Clear, 10 Records per Report Page, and Go to Simple Search buttons.

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Sample Report

1 2 3 4 5 6 7 8 9 10 >

152 records meeting your search criteria returned - ProductCode: dxg

New Search	Export to Excel Download Files More About 510(k)		
↓ Device ↑	↓ Applicant ↑	↓ 510(k) ↑	↓ Decision Date ↑
Modification To Vigileo Arterial Pressur	Edwards Lifesciences, Llc.	K082308	12/09/2008
Transonic Costatus Cardiac Output System	Transonic Systems, Inc.	K080116	09/08/2008
Continuous Cardiac Output Monitor, Truoco	Omega Critical Care Limited	K081776	07/22/2008
Nicom Electrodes	Cheetah Medical Inc.	K071631	01/18/2008
Infinity Picco Pod, Model Ms16734	Draeger Medical Systems, Inc.	K073113	01/03/2008
Pulsion Picco-2, Model 8500	Pulsion Medical Systems Ag	K072735	10/18/2007
Vigileo Arterial Pressure Cardiac Output	Edwards Lifesciences, Llc.	K062134	08/22/2006
Pulsion Picco Plus, Model 8100	Pulsion Medical Systems Ag	K060898	07/25/2006
Ew200 System (Oxygen Saturation Monitor)	Edwards Lifesciences, Llc.	K060660	04/25/2006
Presep And Pediasat Oximetry Catheters A	Edwards Lifesciences, Llc.	K053609	02/28/2006



Sample 510(k) Clearance

New Search	Back To Search Results
Device Classification Name	Computer, Diagnostic, Pre-Programmed, Single-Function
510(K) Number	K082308
Device Name	MODIFICATION TO VIGILEO ARTERIAL PRESSURE CARDIAC OUTPUT/OXIMETRY MONITOR
Applicant	EDWARDS LIFESCIENCES, LLC.
Contact	One Edwards Way Irvine, CA 92614
Regulation Number	Jason Smith
Classification Product Code	870.1435
Subsequent Product Code	DXG
Date Received	DQE
Decision Date	08/13/2008
Decision	12/09/2008
Classification Advisory Committee	Substantially Equivalent (SE)
Review Advisory Committee	Cardiovascular
Statement/Summary/Purged Status	Cardiovascular
Summary Type	Summary Only
Reviewed By Third Party	Summary
Expedited Review	Traditional
	No
	No



PMA Example

Medtronic® Attain StarFix™ Model 4195 Lead - P060039

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Medtronic® Attain StarFix™ Model 4195 Lead
PMA Applicant: Medtronic, Inc.
Address: 1015 Gramco Road, Shoreview, MN 55126-3082
Approval Date: June 13, 2008
Approval Letter: <http://www.fda.gov/cdhr/pd06/p060039a.pdf>

What is it? The Medtronic® Attain StarFix™ Model 4195 Lead is a surgically implanted insulated wire that is designed to be used as a part of a **biventricular pacemaker** system. The 4195 lead is designed to be implanted in a branch of the coronary vein that goes over the surface of the heart's left ventricle. The tip of the lead has lobes that open to help keep it in place. A small amount of steroid (betamethasone dipropionate) at the tip is intended to reduce inflammation of the surrounding tissue. The other end of the lead connects to an implanted biventricular pacemaker or **implantable cardioverter defibrillator (ICD)**, so signals and electrical impulses can be sent between that device and the left ventricle.

How does it work? In some **heart failure** patients, the right and left sides of the heart may not contract together, at the same time. The 4195 lead as part of a biventricular system sends electrical impulses to the heart to promote simultaneous contraction of both ventricles.

When is it used? The Model 4195 lead is used with a compatible implantable pacemaker or implantable cardiac defibrillator to provide chronic pacing and sensing of the left ventricle. Additional leads in other heart chambers are used with the pacemaker to coordinate the entire heart's action at a regular, appropriate rate.

What will it accomplish? The Attain StarFix™ Model 4195 Lead, in conjunction with an implanted pacing device and other leads, helps the heart chambers pump more efficiently by coordinating the timing of contractions. This improved coordination may reduce the symptoms of heart failure and is called cardiac resynchronization therapy, or CRT.

When should it not be used? The Attain StarFix™ Lead Model 4195 should not be used in patients with blocked or inadequate blood vessels for placing leads, or in patients who cannot tolerate a small dose of betamethasone dipropionate (20 µg).

Additional information: The Summary of Safety and Effectiveness and labeling will be available at <http://www.fda.gov/cdhr/pd06/p060039.html>



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Other Key FDA Databases

- Guidance Documents
- Warning Letters
- Panel Meeting Summaries and Transcripts
- Recalls
- New Transparency Website:
 - Total Product Life Cycle
 - De Novo Review Documentation
 - PMA Supplement Review Documentation
 - Post Approval Study Information
 - Proposed by FDA: deficiency letters, IDE information and other information not currently made public

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Clinical Trials.Gov

[Basic Search](#)

Advanced Search

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Fill in any or all of the fields below.

Click on a label to the left for further explanation or read the [Help](#).

Search Terms: [Help](#)

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Study Results: [All Studies](#)

Study Type: [All Studies](#)

Targeted Search:

Conditions:

Interventions:

Outcome Measures:

Lead Sponsors:

Sponsors:

Study IDs:

Exact Match

Exact Match

Locations:

State 1:

Country 1:

State 2:

Country 2:



Key Additional Authority Websites

- Health Canada's Medical Device Site:
<http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php>
- EU MedDev (Guidance on Medical Device Directive):
http://ec.europa.eu/consumers/sectors/medical-devices/documents/index_en.htm
- EU Harmonized Standards: <http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/>
- China SFDA English Website: <http://eng.sfda.gov.cn/eng/>
China Medical Devices Information Network:
<http://www.cmdi.gov.cn/cmdi/lmewen.nsf>
- Japan PMDA English Website: <http://www.pmda.go.jp/english/index.html>
Japan Federation of Medical Devices Associations (JFMDA):
<http://www.jfmda.gr.jp/e/>



Regulator Associations

- Global Harmonization Task Force
- Asia Harmonization Working Party
- ASEAN



Trade/Standards Organizations

- Source of Information
- Conduit for advocacy and influencing legislation, regulations, and guidance
- Joint working groups with regulators
- Opportunity for leadership positions; building credibility with regulators
- Global alliances with other trade associations and standards organizations

- AdvaMed
- MDMA
- Eucomed
- MEDEC
- NEMA
- AAMI
- IEC
- PhRMA
- BIO



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"The Gray Sheet"
Friday, September 11, 2009

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From the Web

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Anderson Independent-Mail
09/11/09 • 21:50 GMT

E-19 Corp. Announces Update to SmallcapInsights.com Article
DIGITAL50
09/11/09 • 21:42 GMT

Six Major Radiology Centers Provide Diagnostic Images to Rochester RHIO Health Management Technology
09/11/09 • 21:41 GMT

Awards clean sweep for county firms
Oxford Times
09/11/09 • 21:32 GMT

DAILY NEWS

FDA Device Center Loses Another Top Staffer
CDRH's associate director for regulations and policy Kate Cook is leaving the device center, the agency said Thursday. She reportedly will join FDA's biologics center [read more >](#)

TOP STORIES

Abbott Gains Synchrony Accommodating IOL Via \$400 Mil. Visiogen Purchase
Abbott will strengthen its premium intraocular lens offerings and enter the accommodating IOL market for the first time through its \$400 million purchase of Visiogen, announced Sept. 2 [read more >](#)

Boston Scientific Expects MADIT-CRT Results To Energize CRM Sales
Boston Scientific is preparing a major sales and marketing effort to support an expanded indication for its cardiac resynchronization therapy devices based on the results of the MADIT-CRT trial [read more >](#)

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 EMAIL SUMMARIES EVERY EVENING*
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FDA-RELATED NEWS

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01/28/2011
- [DDMAC Letters Surged 27% Last Year \[340 Words\]](#)
01/28/2011
- [FDA Grants IDE to Artericyte in Treating Limb Ischemia \[114 Words\]](#)
01/28/2011

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REGULATORY FOCUS
 November 2010 Vol. 13 No. 11
Business Strategy and Regulatory

RAPS Weekly Update >>>
 9 OCTOBER 2010
 Featured Article:
Drugmakers Call for Price Controls in Europe
 The head of the association representing the European pharmaceutical industry has called for price controls that would allow drugmakers to sell medicines cheaply in poorer states without fear of their products being bought and resold at higher prices elsewhere. [More >](#)

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NEWS UPDATES

- Cough and Cold Meds Add Warning for Young Children**
- Study Says Free Drug Samples May Harm Children**
- UK Encourages Drugmakers to Cut Prices for New Drugs**

Upcoming Events

MEETINGS

- 13-14 November 2010
Regulatory Strategy Forum
Chapel Hill, NC
- 4-5 December 2010
Preparing CompleteCTD Submissions
Piscataway, NJ

RAPS NEWS

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Database Providers

- Clinivation (www.clinivation.com)
- IDRAC (www.idrac.com)
- MediRegs (www.mediregs.com)
- PharmaPendium (www.pharmapendium.com)
- Tarius (www.tarius.com)

For details, see RAPS Focus Magazine, December 2007:
Article by Meredith Brown-Tuttle, 2007 Update on
Regulatory Intelligence Databases



Subscription Service Content

- National authorities' regulations, laws, guidances, forms
- In national language, but English metadata available
- Summaries/Explanatory documents written by their experts about the procedures and practicalities
- News service/email alert
- Structured archive of draft, current and superseded docs
- Enable upload of company documents and/or comments



What can a subscription service NOT do?

- Subscription databases are not consultants
- Cannot tell what the implications will be for your company of new regulatory legislation, regulations and guidances
- Cannot advise of the best project strategy for your company

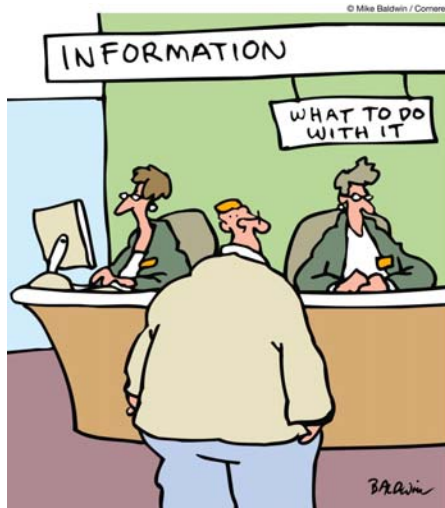


People/Networking

- Your colleagues, consultants, regulators, etc.
- Discussion groups/blogs:
 - www.pharmalot.com
 - www.pharmawebblog.com
 - www.fdalawblog.net
 - <http://druganddevicelaw.blogspot.com/>



Conclusion



- Tons of information available
- Choose wisely
- Make sure it still has relevance



Thank You!

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 - Linda Bowen (sanofi aventis)

For permission to adapt some of their slides from a RAPS Wisconsin Chapter session on Regulatory Intelligence

