Opportunities in Current Medical Device Regulatory Landscape

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Outline

- Changing device regulatory landscape
- Reducing regulatory uncertainties
- Successful approaches

Changing Device Regulatory Landscape

FDASIA 2012 Device Mandates

- IDE Disapproval
- Appeal Timeline
- Clinical Hold
- Direct De Novo
- Reclassification
- Global Harmonization
- Third-Party Review
- HDE Annual Distribution
- Custom Device
- Health IT

Drug Mandate: Expedited Approval

Changing Device Regulatory Landscape

CDRH User-Fee Commitments

- Pre-Submission Process
- Communication Commitments
- Guidance Development
- Third Party Review
- Patient Perspectives
- Exempt Devices
- Emerging In-Vitro Diagnostics

Changing Device Regulatory Landscape

Guidance Documents*

Year	Device Specific	Clarification	New Policy	TOTAL
2010	23	4	3	30
2011	18	6	2	26
2012	**7**	**4**	**5**	16
2013	12	11	7	30
2014	21	24	15	60
2015	6	2	2	10

FDASIA

510(k)
-Acceptance
-Review Clock

PMA
-Acceptance
-Review Clock

*As of 3/6/15, from guidance search page using criterion FDA Organization=CDRH

Changing Device Regulatory Landscape

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Early Feasibility IDE -1st in Human

Mobile Medical Apps

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Changing Device Regulatory Landscape

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Pre-submission Process

IDE Decisions

Review Communications

510(k) – More Exemptions

Direct De Novo

PMA
-Expedited Access
-Pre -> Post

Lab Developed Tests

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Changing Device Regulatory Landscape

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2012	7	4	5	16
2013	12	11	7	30
2014	21	24	15	60
2015	6	1	**3**	10

MDDS, Image Storage & Communication

Accessory

General Wellness

*As of 3/6/15, from guidance search page using criterion FDA Organization=CDRH

Changing Device Regulatory Landscape

Device Advice Webpages

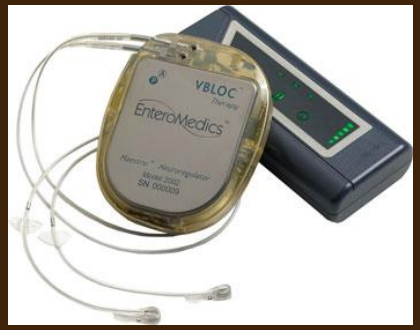
- New IDE SOP
- Changes to device export certification and tracking system

Changing Device Regulatory Landscape

Precedent Setting Decisions

– De Novo

– PMA



Changing Device Regulatory Landscape

Internet-Defamation. Available from: http://re-self.ru/wp-content/uploads/2013/02/ [Accessed 12 March 2015].

Reducing Regulatory Uncertainties

FDA's Decision Summary

- 510(k) Summary
- PMA SSED (Summary of Safety and Effectiveness Data)
- HDE SSPB (Summary of Safety and Probable Benefit)
- De Novo Summary

FOIA

Reducing Regulatory Uncertainties

Guidance*/Device Advice

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2010	23	4	3	30
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2013	12	11	7	30
2014	21	24	15	60
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*As of 3/6/15, from guidance search page using criterion FDA Organization=CDRH

Reducing Regulatory Uncertainties

Standard(s)*

- AAMI (connectors, …)
- ASTM (material, …)
- IEC (electrical, …)
- ISO (biocompatibility, …)
- …

*Device standard search page: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Reducing Regulatory Uncertainties

Q-Sub (Pre-submission process)

- Study Risk Determination
- Binding Agreement or Determination
- Pre- IDE, 510(k), PMA, HDE, or De Novo
- Submission Issue
- Informational Meeting

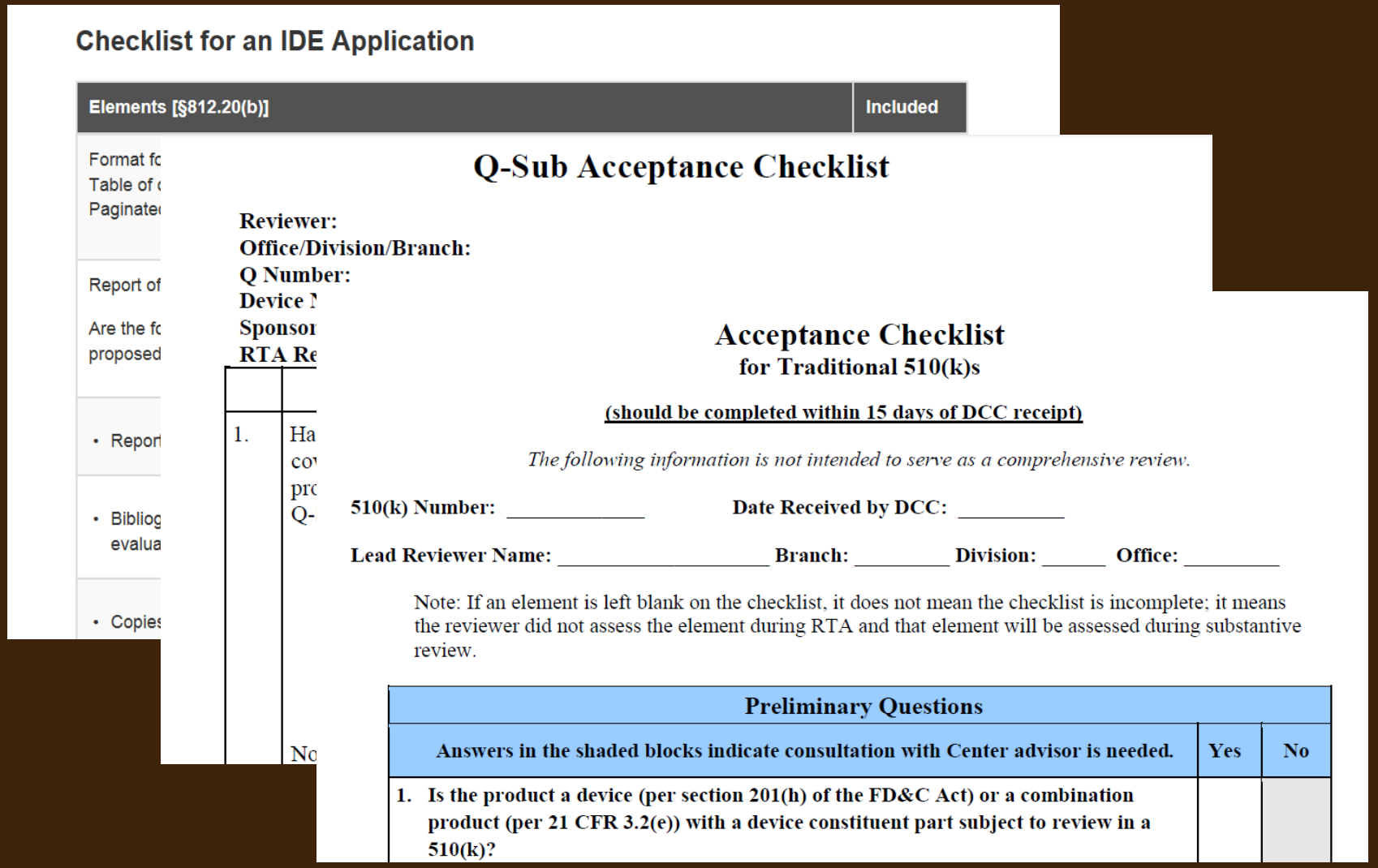
Reducing Regulatory Uncertainties

Others

– Communication Opportunities
– Supervisory Review

Reducing Regulatory Uncertainties

Successful Approaches



Checklist for an IDE Application

Elements [§812.20(b)]	Included
Format fc Table of Paginate	
Report of Are the fc proposed	
• Report	
• Bibliog evalua	
• Copies	

Q-Sub Acceptance Checklist

Reviewer:
Office/Division/Branch:
Q Number:
Device
Sponsor
RTA Re

1.	Ha co pro Q-
	No

Acceptance Checklist
for Traditional 510(k)s

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

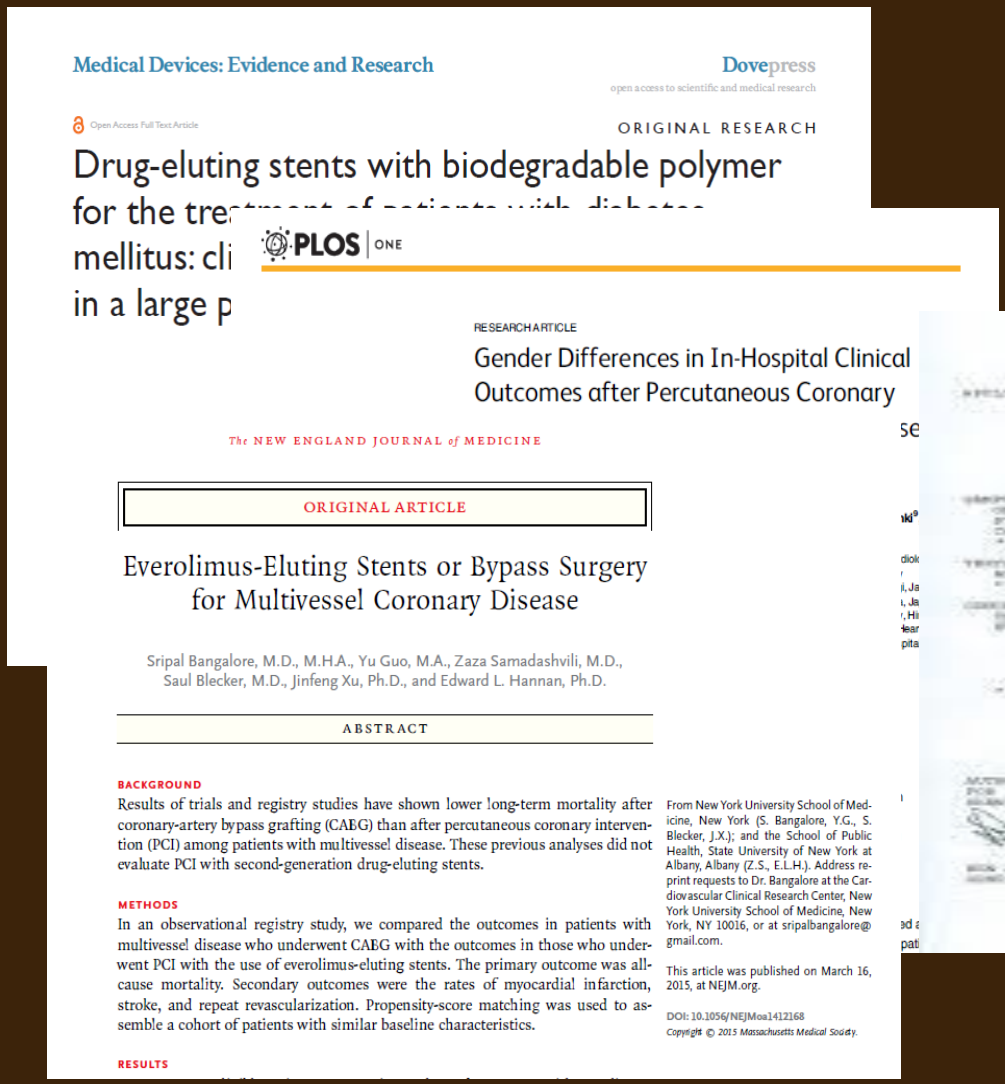
510(k) Number: _____ **Date Received by DCC:** _____

Lead Reviewer Name: _____ **Branch:** _____ **Division:** _____ **Office:** _____

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during RTA and that element will be assessed during substantive review.

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	**Yes**	**No**
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?		

Successful Approaches



Medical Devices: Evidence and Research

Dovepress

open access to scientific and medical research

Open Access Full Text Article

ORIGINAL RESEARCH

Drug-eluting stents with biodegradable polymer for the tre[illegible] mellitus: cli[illegible] in a large p[illegible]

PLOS ONE

RESEARCH ARTICLE

Gender Differences in In-Hospital Clinical Outcomes after Percutaneous Coronary

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Everolimus-Eluting Stents or Bypass Surgery for Multivessel Coronary Disease

Sripal Bangalore, M.D., M.H.A., Yu Guo, M.A., Zaza Samadashvili, M.D., Saul Blecker, M.D., Jinfeng Xu, Ph.D., and Edward L. Hannan, Ph.D.

ABSTRACT

BACKGROUND

Results of trials and registry studies have shown lower long-term mortality after coronary-artery bypass grafting (CABG) than after percutaneous coronary intervention (PCI) among patients with multivessel disease. These previous analyses did not evaluate PCI with second-generation drug-eluting stents.

METHODS

In an observational registry study, we compared the outcomes in patients with multivessel disease who underwent CABG with the outcomes in those who underwent PCI with the use of everolimus-eluting stents. The primary outcome was all-cause mortality. Secondary outcomes were the rates of myocardial infarction, stroke, and repeat revascularization. Propensity-score matching was used to assemble a cohort of patients with similar baseline characteristics.

RESULTS

From New York University School of Medicine, New York (S. Bangalore, Y.G., S. Blecker, J.X.); and the School of Public Health, State University of New York at Albany, Albany (Z.S., E.L.H.). Address reprint requests to Dr. Bangalore at the Cardiovascular Clinical Research Center, New York University School of Medicine, New York, NY 10016, or at sripalbangalore@gmail.com.

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Successful Approaches

Successful Approaches

Thanks!

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