



## RASOR RESOURCE ALERT

### *FDA Deadline for Submission of Safety & Effectiveness Information for Certain Class III Devices*

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Greetings Julia:

This alert is to be sure you are aware that the FDA recently published an Order in the Federal Register requiring manufacturers of twenty-five Class III preamendments devices (see list below) to submit to FDA a summary of, and citation to, any known, or otherwise available, safety or efficacy information, including adverse safety and effectiveness data that has not been submitted. The devices are those Class III preamendment devices for which a final regulation requiring the submission of a PMA has yet to be issued. The summaries and citations are due by **August 7, 2009**.

Based on the information submitted, the FDA will determine whether the device should be reclassified to one of the following conditions:

- *Submission of a PMA (Pre-market Approval)*
- *Notice of completion of Product Development Protocol*
- *Reclassified to Class I or Class II*

A list of what a required submission should include is provided below. We are glad to offer assistance in fulfilling these requirements

**Julia S. Rasor**

Medical Device Strategist and Entrepreneur

Alert: August 7, 2009 FDA Deadline Class III Preamendments Devices

## Background



In 1976, the Medical Device Amendment to the Food, Drug, and Cosmetic Act authorized FDA to evaluate new medical devices. Devices were divided into three classes according to the level of risk each posed, with Class III indicating the highest level of risk. Class III devices are typically evaluated through the Pre-market Approval (PMA) process for safety and effectiveness before being cleared to market, whereas Class I and Class II devices may be deemed substantially equivalent to already-marketed products, a less stringent procedure. The Medical Device Amendments allowed already-existing Class III devices to be put on the market without PMA approval until FDA established rules for bringing them through the process. Recent concerns over the safety of some unevaluated Class III devices contributed to the GAO's recent urging for FDA to move forward with review of these pre-1976 devices.

Affected manufacturers have 120 days to submit a summary of information appropriate to allow FDA to evaluate the risk level posed by the device. Any devices not subsequently reclassified as Class I or Class II must then have PMA applications submitted. Failure to

comply with this order results in the device being misbranded and is a prohibited act. The announcement in the Federal Register can

be viewed at <http://edocket.access.gpo.gov/2009/E9-8022.htm>.

## List of 25 Affected Devices

The April 9, 2009, Order applies to all manufacturers of the device types listed below.

DEVICE TYPE	CLASSIFICATION REGULATION (21 CFR XXX.XXX)	CORRESPONDING PRODUCT CODE(S)
Membrane lung for long-term pulmonary support	868.5610	BYS
Intra-aortic balloon and control system	870.3535	DSP, NKO
Ventricular bypass (assist) device	870.3545	OKR
External pacemaker pulse generator	870.3600	DTE
Implantable pacemaker pulse generator	870.3610	DSZ, DXY
Endosseous dental implant (blade-form)	872.3640(b)(2)	NRQ
Cardiovascular permanent pacemaker electrode	870.3680(b)	DTB
Pacemaker programmers	870.3700	KRG
Pacemaker repair or replacement material	870.3710	KFJ
Mandibular condyle prosthesis (for temporary reconstruction)	872.3960(c)(2)	NEI
Nonroller-type cardiopulmonary bypass blood pump	870.4360	KFM
External cardiac compressor	870.5200	LIX, DRM
External counter-pulsating device	870.5225	DRN
Automated external defibrillator	870.5310	NPN, NSA, MKJ
Implanted blood access device	876.5540(b)(1)	NIF, MSD, NYU, FJM, FJN, FJO, FJQ, LTH, FIQ, NNF, FKN, FKW, KNR, KNZ, LBW, LFJ
Sorbent hemoperfusion system	876.5870	FLD
Cranial electrotherapy stimulator	882.5800	JXK
Electroconvulsive therapy device	882.5940	GXC
Female condom	884.5330	OBY
Pedicle screw spinal system (certain uses)	888.3070(b)(2)	NKB
Hip joint metal/metal semi-constrained, with a <i>cemented</i> acetabular component, prosthesis	888.3320	JDL, LTO
Hip joint metal/metal semi-constrained, with an <i>uncemented</i> acetabular component, prosthesis	888.3330	KWA
Shortwave diathermy (certain uses)	890.5290(b)	ILX
Iontophoresis device (certain uses)	890.5525(b)	EGJ
Transilluminator for breast evaluation	892.1990	LEK

## What a Required Submission Should Include

A manufacturer of a device listed in the above table must submit the information detailed here.

### 1. Indications for use.

A general description of the disease or condition to be diagnosed, treated, cured, mitigated, or prevented, including a description of the patient population for which the device is intended.

### 2. Device description.

An explanation of how the device functions, significant physical and performance characteristics of the device, and basic scientific concepts that form the basis for the device.

### 3. Other device labeling.

Other device labeling that includes contraindications, warnings and precautions and/or promotional materials.

### 4. Risks.

A summary of all adverse safety and effectiveness information and identification of the risks presented by the device as well as any mechanisms or procedures which will control the risk.

### 5. Alternative practices and procedures.

A description of alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended.

### 6. Summary of preclinical and clinical data.

The summary of preclinical and clinical data should include the conclusions drawn from the studies that support the safety and

effectiveness of the device, and that address the adverse effects of the device on health.

The summary should include a brief description of the objective of the studies, the experimental design, how the data were collected and analyzed, and a brief description of the results of the studies, whether positive, negative, or inconclusive.

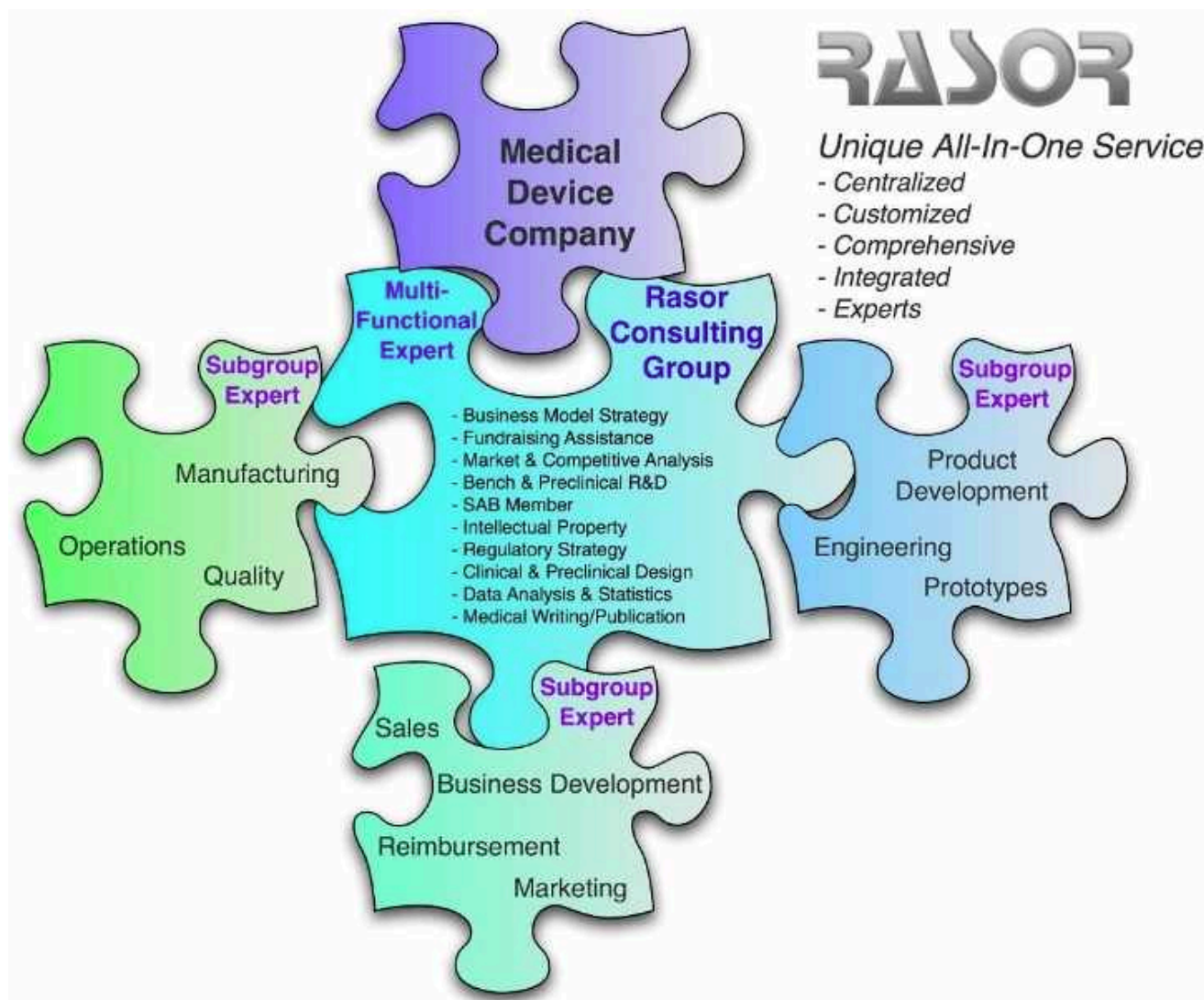
The summary of the clinical study should also include a discussion of the subject inclusion and exclusion criteria, the study population, reasons for patient discontinuations, and results of statistical analyses.

**7. Bibliography.**

A copy of each key reference, a brief summary of the salient features of each key reference, and a brief discussion of why the reference is relevant to an evaluation of the safety and effectiveness of the device.

If a manufacturer is aware of adequate and valid scientific information that would support the reclassification of the device into class I or class II, the manufacturer may either submit information located at <http://www.fda.gov/cdrh/classiii.html#3> or submit a formal reclassification petition, as described in 21 CFR 860.123(a)(3)-(4).

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Julia S. Rasor, MSc, is a multifunctional strategic entrepreneur with a track record of leading very successful solutions for business, clinical, and regulatory roadblocks. She is the inventor of a \$100M-a-year revenue medical product, holder of 6 patents with 7 pending, former CEO founder, member of five scientific advisory boards, founder of the 25-year Rasor Consulting Group at [MedicalDevice.com](http://www.MedicalDevice.com), and author of 50 publications.

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