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MEMORANDUMVia E-Mail

DATE: April 10, 2009

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: FDA Announces Action on Reclassification of Certain Medical Devices

In a *Federal Register* notice issued April 9, 2009, the Food and Drug Administration (FDA) announced plans regarding the future reclassification of 25 Class III Medical Devices marketed since before the enactment of the Medical Device Amendments in 1976.¹ Those amendments permitted the devices in question, many of which are implants, life supporting or sustaining devices, or devices that present a potential unreasonable risk to health, to remain in commerce until FDA decided whether to reclassify them into lesser regulatory categories or require the submission of a Premarket Approval Application (PMA) to obtain approval to continue to market. Subsequent devices of the same type were permitted to be marketed on the strength of a Premarket Notification or 510(k) notice until a decision was reached on final classification. Such a notice requires a lesser burden of proof than does a PMA. Various members of Congress, public health advocates, and other interested parties have been critical of FDA's failure to complete the reclassification, so that more evidence could be made available to support the marketing of the more hazardous of the pre-enactment products.

Congress first called for FDA to act in 1990. In 2007, Congress mandated that the General Accountability Office (GAO) study the 510(k) process and make recommendations for regulations to address the reclassification that had been ongoing without resolution for a total of 31 years. GAO issued its report in January of this year, recommending that FDA move expeditiously to issue regulations either to reclassify some or all of the 25 types of devices in question or call for the submission of a PMA to obtain approval to market.²

¹ 74 Fed. Reg. 16214 (Apr. 9, 2009).

² GAO, MEDICAL DEVICES: "FDA Should Take Steps to Ensure That High Risk Device Types Are Approved through the Most Stringent Premarket Review Process," GAO-09-190 (Jan. 2009), available at <http://www.gao.gov/new.items/d09190.pdf>.



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The *Federal Register* notice is in response to GAO's recommendations. According to the notice, manufacturers must submit by **August 7, 2009**, "a summary of, and a citation to, any information known or otherwise available to them respecting such devices, including adverse safety or effectiveness information concerning the devices which has not been submitted under the Federal Food, Drug, and Cosmetic Act."³ The notice states that FDA "does not anticipate extending the time for submitting the required information."⁴

The 25 devices, listed by the section of the Code of Federal Regulations where they are described, are as follows:

1. 21 CFR 868.5610 Membrane lung for long-term pulmonary support.
2. 21 CFR 870.3535 Intra-aortic balloon and control system.
3. 21 CFR 870.3545 Ventricular bypass (assist) device.
4. 21 CFR 870.3600 External pacemaker pulse generator.
5. 21 CFR 870.3610 Implantable pacemaker pulse generator.
6. 21 CFR 870.3680(b) Cardiovascular permanent pacemaker electrode.
7. 21 CFR 870.3700 Pacemaker programmers.
8. 21 CFR 870.3710 Pacemaker repair or replacement material.
9. 21 CFR 870.4360 Nonroller-type cardiopulmonary bypass blood pump.
10. 21 CFR 870.5200 External cardiac compressor.
11. 21 CFR 870.5225 External counter-pulsating device.
12. 21 CFR 870.5310 Automated external defibrillator.
13. 21 CFR 872.3640(b)(2) Endosseous dental implant (blade form).

³ 74 Fed. Reg. at 16214-16215.

⁴ 74 Fed. Reg. at 16216.



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14. 21 CFR 872.3960 Mandibular condyle prosthesis (temporary implant).
15. 21 CFR 876.5540(b)(1) Implanted blood access device.
16. 21 CFR 876.5870 Sorbent hemoperfusion system.
17. 21 CFR 882.5800 Cranial electrotherapy stimulator.
18. 21 CFR 882.5940 Electroconvulsive therapy device.
19. 21 CFR 884.5330 Female condom.
20. 21 CFR 888.3070(b)(2) Pedicle screw spinal system (certain uses).
21. 21 CFR 888.3320 Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.
22. 21 CFR 888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.
23. 21 CFR 890.5290(b) Shortwave diathermy (certain uses).
24. 21 CFR 890.5525(b) Iontophoresis device (certain uses).
25. 892.1990 Transilluminator for breast evaluation.⁵

The notice lists the information that is required to be submitted. The information is substantial, and manufacturers that market any of the devices listed above should proceed to develop the information required as soon as possible.

If you have questions or need assistance in preparing your submission, you may contact Lynn L. Bergeson (lbergeson@lawbc.com) or Michael F. Cole (mcole@lawbc.com) at Bergeson & Campbell, P.C. Mr. Cole has been involved with medical device issues since the drafting of the original legislation in 1976 that gave rise to the present classification issue.

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⁵ *Id.*



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We hope this information is helpful. As always, please let us know if you have any questions.