Oakwood Hospital
& Medical Center

18101 Oakwood Blvd.
P.O. Box 2500
Dearborn, Michigan
48123-2500

313.593.7000

Oakwood

0220 7 JUN -6 A10:17

To whom it may concern:

This letter is in reference to Docket No. 2006N-0362, the proposed reclassification of absorbable hemostatic devices from class III to class II. This proposed change would allow these devices to hereby forego the regulatory process in place for class III devices (clinical evaluation and approval) to ensure product safety. In effect, this would create the possibility of a device entering the OR without prior testing. This could affect not only the outcome of hemostatic procedures, but also the safety of patients undergoing these procedures.

Because the proposed reclassification does not require absorbable hemostatic devices to go through clinical evaluation and approval, new devices could be cleared with labeling that excludes common uses of the devices currently available. While the FDA will require labeling to limit the use of these newer products, the possibility exists that surgeons will use the untested devices the way they have previously used the devices with which they are familiar—according to their standard practice.

Due to the reasons outlined above, I am against the reclassification of absorbable hemostatic devices from class III to class II. It is my hope that the FDA will reconsider this proposal and keep these devices as class III.

Thanks for your time and attention to this matter.

Sincerely,

MD

Timothy L. Sell, MD

2006N-0362

C20