



Wayne State University
School of Medicine

Fernando G. Diaz, M.D., Ph.D.
Professor and Chairman

Neurological Surgery Department
Harper Professional Building
4160 John R. Suite 930
Detroit, Michigan 48201

Off ice: (313) 966-0343
Fax: (313) 966-0368
Clinic: (313) 745-4266
Fax: (313) 993-0303

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Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

**RE: Use of Bone Grafts as Medical Devices
Docket #97N484S**

Dear Sirs:

I have received a communication from Medtronic Corporation in which they indicate that your office is currently processing regulations regarding the use of bone allografts as medical devices. Assuming that the cumbersome government requirements become a necessity for the use of bone allografts, this could create a severe shortfall for the use of bone graft for patients. We perform approximately 50 surgeries per week, for which there is a need for a bone allograft in about a fourth of them. It is indispensable that the bone allografts remain accessible and available to physicians, since otherwise this will create a severe problem for patients who frequently are unable to provide for their own bone source.

I urge you to look at this serious problem, and be supportive of the needs of the patients and the physicians who care for them.

Sincerely,

Fernando G. Diaz, M.D., Ph.D.
Professor and Chairman
Department of Neurological Surgery
Wayne State University
School of Medicine

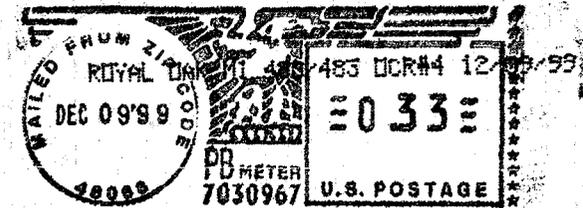
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Wayne State University
School of Medicine
Department of Neurosurgery
University Health Center
4201 St. Antoine, 6E
Detroit, Michigan 48201



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5 63 0 Fishers Lane
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