



Christopher **M. Bieniek**, M.D.
Curtis **D. Burton**, M.D.
Richard **V. Davis**, M.D.

P.O. Box 935

Hannibal, Missouri 63401

9547 Phone: 573/248-1010 :18

Fax: 573/248-0536

December 1, 1999

Document Management Branch
H.F.A.A. - 305
Food and Drug Administration
5630 Fisher's Lane - Room 1061
Rockville, Maryland 20852

RE: Docket No. 97N-484S

Dear Sir:

I understand there is a pending proposal to regulate the use of Allograft and classify it as a medical device. As a physician who routinely uses Allograft in my practice I do not believe that this will be helpful or protective to patients in my practice. I think this has the potential to limit the supply of bone product on which we rely for treating patients.

I would certainly appreciate it if you would send me the rationale of the potential benefits of reclassifying bone Allograft.

Thank you very much.

Sincerely,

A handwritten signature in black ink, appearing to read "Curtis D. Burton, M.D.", written in a cursive style.

Curtis D. Burton, M.D., F.A.C.S.

CDB/lb

cc: Ron Pickard, President
Medtronic

97N 484S

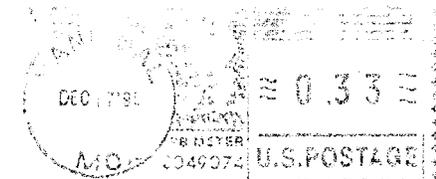
C 263



Christopher M. **Bieniek**, M.D.
Curtis D. Burton, M.D.
Richard V. Davis, M.D.

P.O. Box 935

Hannibal, Missouri 63401



Document Management Branch
H.F.A.A. -305
Food and Drug Administration
5630 Fisher's Lane - Room 1061
Rockville, Maryland 20852

20857-0001

