



# Central Minnesota Neurosciences Ltd.

Neurosurgery  
A. Reginald Watts, MD, FRCS (C)  
Jeffrey S. Gerdes, MD

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February 29, 2000

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

RE: Docket #97N-484S

TO WHOM IT MAY CONCERN:

I received a mass mailing from John W. Brantigan, M.D.

I am very significantly concerned by this mailing and the prejudicial nature of this mailing.

As surgeons, we have been using bone allograft for a great number of years with great success. There seems to be a considerable discrepancy in Dr. Brantigan's message. It seems apparent that the real issue with Dr. Brantigan is whether the allograft is obtained from the Red Cross or some other tissue banks, or whether it is obtained from the Danek Corporation.

Dr. Brantigan's complaint that some companies have raised the issue that non-regulation of the threaded allografts is unfair, and I believe this is nothing but self-serving.

With respect to the BAK cage, which Dr. Brantigan is undoubtedly backing, I have had some particular concerns with respect to this device personally. The BAK cage is made far too strong and therefore does not allow the autogenous bone to be adequately stressed to heal fully. As well, I believe the thread is entirely wrong for bone. The Acme or square thread which this cage uses is a great thread for metal, but for tissues such as wood and bone, the thread needed is not a square thread of fine pitch, but a deep V thread of more coarse pitch.

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In my opinion, we had a much better cage on the market, the Ray cage, which was apparently killed by BAK on a patent dispute. The Ray cage had the deep V thread, greater bone contact between the adjacent vertebra through the cage, and walls to occlude the sides of the cage to prevent ingrowth of tissue from the discs that would destroy the graft. As well, this cage was not quite as sturdy as the BAK cage, and this was done intentionally to allow the autograft bone to be stressed to improve healing.

As a surgeon who has used a great number of these dowels and has had considerably better than the 60% fusion rate Dr. Brantigan claims, I would strongly urge the FDA to leave the allograft bone unregulated and relegate Dr. Brantigan's letter to the trash can that it so rightly deserves.

Many thanks. Personal regards.

Yours very truly,

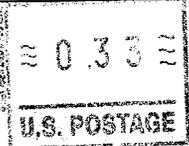
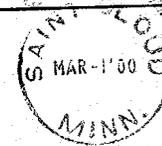
  
A.R. Watts, M.D., F.R.C.S.(C)

ARW/gcg



CENTRAL MINNESOTA NEUROSCIENCES, LTD.

1400 WEST ST. GERMAIN  
SAINT CLOUD, MINNESOTA 56301



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