

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

December 8, 2004

Randall Everett, President
Diomedics, Inc.
755 State Road 21
North Melrose, Florida 32666


Dear Mr. Everett:

We have completed our review of your firm's letter dated November 29, 2004, which was provided in response to Warning Letter #FLA-04-25 issued to you on March 29, 2004. Your response has been made part of the Florida District file.

We find that your response appears to adequately address the QS regulation observations. We reviewed your labels and find that all unapproved claims previously used to promote your devices for indications outside the scope of your device clearance have been removed. We will verify your promised corrections during the next scheduled inspection of your facility.

For further information, please contact the undersigned at the U. S. Food and Drug Administration, 555 Winderley Place, Suite #200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,


Timothy J. Cousins
Compliance Officer
Florida District