DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1350 Piccard Drive
Rockville MD 20850

April 14, 1999

Stephen M. Dolle
3908 ½ River Avenue
Newport Beach, California 92663

Dear Mr. Dolle:

In response to your February 5, 1999 letter I have reviewed your request and appreciate your support of the Systematic Technology Assessment of Medical Products (STAMP) program. In your letter you identify three items that you would like our comments. The first item, you report the importance of further coverage and public relations for the STAMP program. We recognize this importance and agree that providing a positive change in patient outcome through the implementation of STAMP requires active promotion. We are actively involved in implementing and promoting this important program and welcome further support and comment.

Your second item describes the need for routine home monitoring. We certainly support any activity that results in a more informed patient; however, the Center for Devices and Radiological Health (CDRH) does not have the authority to endorse a medical product. However, CDRH does have the authority under the Food, Drug and Cosmetic Act to request that any medical device intended for market be evaluated to assure a reasonable assurance of safety and effectiveness prior to market release. The concept of a system you describe in your letter and in the paper you enclosed has merit and therefore I recommend you consult with the Office of Device Evaluation to determine what premarket requirements are necessary to obtain market clearance/approval. The appropriate contact information is supplied below:

Division of General and Restorative Devices
Office of Device Evaluation
9200 Corporate Blvd, HFZ-410
Rockville, Maryland 20850
Tel. 301-594-1184
Fax. 301-594-2358

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Finally, in your third item you request that the paper you provided for distribution at the conference, "Shunt Technology: Challenges and Emerging Directions," held on January 8, 1999, be included as part of our comments of the conference in the conference summary. Your paper raised several interesting points regarding some of the short-comings of the current shunt technology and the need to improve patient outcome. The

announcement of this conference peaked the interest of many interested in improving patient outcomes with respect to the treatment of hydrocephalus. We received numerous requests to submit papers and give presentations at the conference. Although our agenda did not allow all to give presentations we did provide the opportunity for all who requested to distribute papers on their work. Unfortunately including all of these papers in the conference summary making the summary excessive in length. Therefore, it was decided that the summary include a summary of the presentations only and an article may be written to address the recommendations and comments shared during the conference.

Thank you again for your interest and support in the STAMP program and the ongoing efforts to improve shunt technology and patient outcomes.

Sincerely,

Larry G. Kessler, ScD.
Director
Office of Surveillance and Biometrics
Center for Devices and Radiological Health