



DIVISION OF  
CORPORATION FINANCE

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

December 14, 2010

Manny Villafana  
Chairman and Chief Executive Officer  
Kips Bay Medical, Inc.  
3405 Annapolis Lane North, Suite 200  
Minneapolis, Minnesota, 55447

**Re: Kips Bay Medical, Inc.  
Amendment No. 6 to Registration Statement on Form S-1  
Filed November 30, 2010  
File No. 333-165940**

Dear Mr. Villafana:

We have reviewed your amended registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

Intellectual Property, page 2

1. Please revise to clarify that while it is your *belief* that the BPAI reversal supports your position with respect to your other pending patent applications, neither the BPAI nor other applicable body has issued (or as yet indicated that it intends to issue) reversals with respect to these applications.

Clinical Development of Our ESVS MESH, page 3

2. Refer to prior comment 3. It remains unclear why the final results did not impact the status of your CE Mark. With a view to disclosure, please tell us whether you disclosed the final results, your modification of instructions, your determination to cease using your 3.0 mm

mesh and your reduction in downsizing to the Notified Body. If you did not disclose such results please provide your analysis explaining how you determined such disclosure is not required. In addition, please:

- Identify the relevant Notified Body.
- Clarify whether the Notified Body issued your application with an EC design-examination certificate and, if so, please provide a copy to us;
- Clarify whether there were any conditions to the validity of such certificate; and
- Clarify whether the Notified Body required any further tests or proof regarding your device.

Recent Developments, page 5

3. We note your response to prior comment 4. Please revise the disclosure in your business section to disclose the material terms of your distributor agreements, including exclusivity rights and term and termination provisions. To the extent that distributor rights in certain countries are exclusive or regions significant to your business are otherwise covered by one or a few distributors, please expand your analysis to explain why these distribution agreements should not be deemed material.

If we are unable to successfully complete our clinical trials..., page 8

4. Please revise the caption of this risk factor to disclose that the results of your one human clinical trial were inconclusive. Make similar revisions throughout the prospectus, as appropriate, to clarify that the results of the trial were inconclusive.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes the information the Securities Act of 1933 and all applicable Securities Act rules require. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

Notwithstanding our comments, in the event you request acceleration of the effective date of the pending registration statement please provide a written statement from the company acknowledging that:

- should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;

Manny Villafana  
Kips Bay Medical, Inc.  
December 14, 2010  
Page 3

- the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- the company may not assert staff comments and the declaration of effectiveness as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please refer to Rules 460 and 461 regarding requests for acceleration. We will consider a written request for acceleration of the effective date of the registration statement as confirmation of the fact that those requesting acceleration are aware of their respective responsibilities under the Securities Act of 1933 and the Securities Exchange Act of 1934 as they relate to the proposed public offering of the securities specified in the above registration statement. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Julie Sherman at (202) 551-3640 or Jeffrey Jaramillo, Accounting Branch Chief, at (202) 551-3212 if you have questions regarding comments on the financial statements and related matters. Please contact Ruairi Regan at (202) 551-3269 or Daniel Morris, Special Counsel, at (202) 551-3314 with any other questions.

Sincerely,

Martin James  
Acting Assistant Director

cc (by facsimile): Robert K. Ranum, Esq.