DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Synthes Spine Co.
% Mr. Jason Lipman
Regulatory Affairs Specialist
1302 Wright's Lane East
West Chester, Pennsylvania 19380

MAY 2 5 2007

Re: H030009/S004
HUD19970014
Vertical Expandable Prosthetic Titanium Rib (VEPTR)
Filed: March 15, 2007
Amended: May 14, 2007

Dear Mr. Lipman:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your humanitarian device exemption application (HDE) supplement, which requested approval for minor component modifications and related changes to the labeling for the Vertical Expandable Prosthetic Titanium Rib (VEPTR). The device, as modified, will be marketed under the trade name Vertical Expandable Prosthetic Titanium Rib II (VEPTR II) and is indicated for the treatment of Thoracic Insufficiency Syndrome (TIS) in skeletally immature patients. TIS is defined as the inability of the thorax to support normal respiration or lung growth. For the purpose of identifying potential TIS patients, the categories in which TIS patients fall are as follows:

- Flail Chest Syndrome
- Constrictive Chest Wall Syndrome, including
  - Rib fusion and scoliosis
- Hypoplastic thorax syndrome, including
  - Jeune's syndrome
  - Achondroplasia
  - Jarcho-Levin syndrome
  - Ellis van Creveld syndrome
- Progressive scoliosis of congenital or neurogenic origin without rib anomaly

Based upon the information submitted, the HDE supplement is approved subject to the conditions described in the approval order for your original HDE. You may begin commercial distribution of the device as modified by your HDE supplement upon receipt of this letter.

Failure to comply with the conditions of approval as described in the approval order for the original HDE invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Federal Food, Drug, and Cosmetic Act.

You are reminded that as soon as possible and before commercial distribution of your device you must submit an amendment to this HDE with copies of all approved labeling in final form. The labeling will not routinely be reviewed by FDA staff when HDE supplement applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and reference the above HDE number to facilitate processing.

HDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Ronald P. Jean, Ph.D. at (240) 276-3676.

Sincerely yours,

Barbara Buch MD
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health