DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Synthes Spine Co., LP
% Ms. Stacey Bonnell
Senior Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

FEB 2 4 2012

Re: H030009/S008
Vertical Expandable Prosthetic Titanium Rib (VEPTR)
Filed: August 25, 2011
Amended: January 23, 2012

Dear Ms. Bonnell:

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 MR Conditional labeling 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, and 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

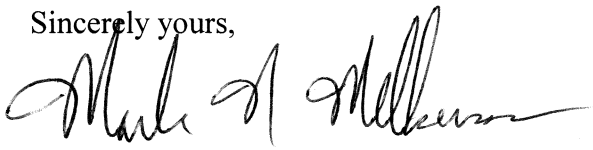
labeling should be highlighted and explained in the amendment.

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

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval letter, please contact Colin O'Neill at (301) 796-6428.

Sincerely yours,



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