

## Humanitarian Device Exemption (H030009) – Vertical Expandable Prosthetic Titanium Rib (VEPTR)

IRB# 2007-025

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### Synopsis:

A Humanitarian Use Device (HUD) is a device used to diagnose or treat a disease or condition that affects fewer than 4,000 individuals in the United States per year and for which no comparable device is available. The U.S. Food and Drug Administration (FDA) approves the use of Humanitarian Devices based primarily on evidence that it does not pose a significant risk of injury to the patient and that the potential benefit of the device to the health of the patient outweighs the risks of its use.

The use of the VEPTR is indicated for treatment of Thoracic Insufficiency Syndrome (TIS) in skeletally immature patients. TIS is defined as the inability for 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