

## ***FDA CONSULTANTS***

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Terry A. Clyburn, M.D.  
Hermann Professional Building  
6410 Fannin, Suite 1100  
Houston, TX. 77030

Date: March 6, 2000

Dear Dr. Clyburn,

**Re: Regulatory Analysis for  
Hip Grip Table**


I evaluated the specifications of Hip Grip Table. The device is similar to 21 CFR 878.4950, Manual Operating Table and Accessories and Manual Operating Chair and Accessories. These are non-powered devices, usually with movable components, intended to support a patient during diagnostic examinations or surgical procedures. These devices are currently Class I Medical Devices. Your device has the following additional features compared to conventional designs:

1. Angulated arms rather than 90° arms, that allow the surgeon greater access to the surgical site.
2. Simultaneous Anterior/Posterior gripping action of the patient during surgery.
3. Table to lay surgical instruments.

I believe that all of the additional features anticipated for your device would not change the Class I classification.

A Class 1 Medical Device is exempt from Section 510(k) of the Food, Drug, and Cosmetic Act. As a result, you may market your Hip Grip Table without prior FDA notification. If you have any questions, please call at your convenience.

Regards,



Xavier A. Adame

Enclosures:

21 CFR Part 878, (4-1-99 Edition), 878.4950 - Manual Operating Table and Accessories and Manual Operating Chair and Accessories.