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510(k) and GMP Exemption

The purpose of this abstract is to determine whether the Safety Ingenuity LLC VersaPad is exempt under *Federal Drug Administration* rules and regulations. On January 20, 2017 I registered with the *Federal Drug Administration* as an account holder. My account ID was SAF72764. I thereafter reviewed provisions of the Food and Drug Administration Modernization Act of 1997 and the 20th Century Cures Act of 2016; and several of the Title 21 regulations. The purpose of this review was to determine whether or not the VersaPad qualified for a "510 K exemption" and a Good Manufacturing Practice Quality System "GMP" exemption. I determined that the VersaPad was exempt from the premarket FDA notification requirements.

I reviewed all class one and class two exemption categories, particularly part 880 General Hospital and Personal Use Devices and part 890 Physical Medicine Devices. In this process part 880.6060 Medical Disposal Bedding Patient Transfer Device, fits precisely the intended usage of the Versapad. Below are the textual requirements of this exemption. (See attachments.)

21 CFR 880.6060

General Hospital and Personal Use Miscellaneous Devices:

Medical disposable bedding
(a) Identification. Medical disposable bedding is a device intended for medical purposes to be used by one patient for a period of time and then discarded. This generic type of device may include disposable bedsheets, bedpads, pillows and pillowcases, blankets, emergency rescue blankets, or waterproof sheets.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of 820.180, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

Code of Federal Regulations, Title 21, Volume 8, [Revised as of April 1, 2017]

Very truly yours,

GARRETT & JENSEN

By **SIGNED DIGITALLY**
BOYD F. JENSEN II

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