FERGUSON MEDICAL

K960421

APR 16 1997

20 December 1995

510(k) SUMMARY

The 510(k) summary information required by 21 CFR 807.92 is as follows:

A. Classification name: Ultrasonic pulsed imaging system, or sinus ultrasound device.

Common/usual name: Ultrasonic sinusitis detector, ultrasound sinus monitor, and others.

Proprietary name: Sinuscan 102/Sinusprint.

B. Substantial equivalence: Various ultrasound scanners and radiographic/CT devices. Enterscan ultrasound sinus device by Pie Data, K874081.

C. Device description: The Oriola Sinuscan 102/ Sinusprint is a pulsed ultrasound scanner.

D. Intended use: The Oriola Sinuscan 102/Sinusprint device is intended for use in the ultrasound detection of frontal and maxillary sinusitis.

E. Technological Characteristics: The Oriola Sinuscan 102/Sinusprint device functions by sending pulses of ultrasonic energy and

3407 Bay Avenue • Chico, California 95926 USA
Phone: (916) 342-4133 • FAX: (916) 343-4541

receiving echoes from acoustic interfaces in the manner of an echo sounder. The reflected echoes are converted to an electric signal and presented as a graph on the LCD display and/or printed by the printer.

Submitted,
FERGUSON MEDICAL
FDA Establishment Registration Number 2937794

Frank Ferguson
Official Correspondent