K945796

Attachment 1

510(k) Summary of Safety and Effectiveness

1.0 SUBMITTER INFORMATION:

1.1 Submitter: Sharplan Lasers, Inc.
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1.2 Contact: Doug Mead

1.3 Date: November 24, 1994

2.0 DEVICE NAME

2.1 Classification Panel: Radiology

2.2 Classification Number: 892.1560 Ultrasonic Pulsed Echo Imaging System
892.1570 Diagnostic Ultrasound Transducer

2.3 Product Number: 90IYO

2.4 Product Nomenclature: System, Imaging, Pulsed Echo, Ultrasonic

2.5 Trade/Proprietary Name: Sharplan uSight 9010 Laparoscopic Ultrasound System

2.6 Predicate Device: Aloka SSD650CL
Bruel and Kjaer System 3535
Endomedix Laparoscan U4000F,S
Tetrad E/U

3.0 DEVICE DESCRIPTION:

3.1 FUNCTION

A wave is a mechanical disturbance of a medium which passes through the medium at a fixed velocity. The rate at which the particles in the medium vibrate in the disturbance is the frequency of the wave, and is measured as cycles/second, or hertz (Hz). Frequencies above 20kHz are no longer audible, and above this frequency, the disturbance is known as ultrasound. For the purposes of medical ultrasound imaging, frequencies of 1–20MHz are utilized.

The basic principle of ultrasound imaging is to generate an ultrasound pulse with an electronic or electromechanical transducer, direct the pulse through a certain medium, then analyze the echoes reflected to the same transducer from various objects along the path of the pulse.

Ultrasound waves (a beam) travel in a straight line in a homogeneous medium. When the beam reaches an interface between two media of different densities, some of the beam passes on through the boundary (refraction), and some is reflected. The degree of reflection is determined by the angle of incidence of the ultrasound beam, and upon the Acoustic Impedance of the two media. Acoustic impedance is defined to be the product of the velocity of sound and the density of the medium. A large difference in acoustic impedance, such as may be found at soft tissue-bone or soft tissue-air interfaces, results in a high degree of reflection. A lesser degree of reflection occurs at boundaries between two different types of soft tissue, for example, muscle-fat.

The ultrasound transducer intermittently generates an ultrasound wave at a predetermined rate, referred to as the pulse repetition frequency (PRF). In the time duration that the transducer is not transmitting pulses, it acts as a receiver for the reflected waves. When an ultrasound wave is emitted from the transducer, the ultrasound system measures the time interval elapsed between emission of the ultrasound pulse and reception of the reflected echoes. Given the speed of the propagation of the ultrasound wave in tissue, (approximately 1540 m/sec), the ultrasound system can estimate the depth location of the object or tissue interface which reflected the wave. The amplitude of the echo is determined by the structure and physical composition of the reflecting tissue, and therefore, it is the amplitude that is of diagnostic significance in determining the brightness of that portion of the displayed image.

An ultrasound system consists of the following:

- an ultrasound transducer(s) used to generate the ultrasound waves and receive the reflected echoes
- a computer system to control the transducer and analyze the reflected signals
- a video monitor with optional image recorder to display the final images

3.2 SCIENTIFIC CONCEPTS

Tissues can be altered or damaged by ultrasound of suffieciently high intensity, through one of the following physical mechanisms:

1. heating
2. radiation force
3. streaming
4. stable cavitation
5. transient (unstable) cavitation

6. standing wave effects

7. non-linear effects

8. direct effects

From past and on-going investigations of these physical mechanisms and their possible biological effects, safe levels of ultrasound for diagnostic purposes have been determined. In October, 1991, the Center for Devices and Radiological Health issued its "510(k) Diagnostic Ultrasound Guidance Update of 1991." In this guidance document, ultrasound system manufacturers have the choice of one of two transducer acoustic output limits:

1. Transducer acoustic outputs limited to 1976 pre-Amendments values–application specific:

Intended Use	Derated Ispta (mW/cm2)	Derated Isppa (W/cm2)
Peripheral Vessel	720	190
Cardiac	430	190
Fetal Abdominal Intra-operative Pediatric Small Organ ❄ Neonatal Cephalic Adult Cephalic	94	190
Opthalmic	17	28

❄ breast, thyroid, testes, etc.

2. Transducer acoustic outputs limited to 1976 pre-Amendments values–non-application specific

The ultrasound system described above will not exceed any of these values for choice #1 above during operation.

3.3 PHYSICAL AND PERFORMANCE CHARACTERISTICS

Ultrasound is currently of great interest because it is capable of producing high quality anatomical images without the associated risks of ionizing radiation. Ultrasound systems have been in clinical use since the early 1970's, and a significant body of publications have been written on the principles of Ultrasound imaging, its development as a diagnostic tool, its clinical uses, and on its relative safety.

Alternative procedures for comparison with the Ultrasound system include all other diagnostic imaging modalities, including standard radiography, angiography, magnetic resonance, nuclear medicine, and x-ray computed tomography (CT).

4.0 DEVICE INTENDED USE:

The Ultrasound system is an imaging device, and is intended to provide the physician with clinical information, obtained non-invasively and without the use of ionizing radiation. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination and surgery planning.

In order to ensure the availability for evaluating the accuracy of ultrasound imaging results, intended patients are those for whom it is anticipated that adequate, independent confirmation of any lesion apparently detected with the ultrasound system can be obtained. With the exception of normal volunteers, eligible patients must have suspected or documented neoplastic, degenerative, infectious, or developmental disease process strongly suspected or established by physical exam, history, or conventional histologic, biochemical, bacteriological, or imaging techniques, or have surgical or aspiration biopsy pending that will be used to establish a diagnosis. The intended patients are primarily drawn from a pool of those subjects undergoing diagnostic evaluation by physicians who are skilled in diagnosis and treatment of the disease process(es) under consideration.

5.0 DEVICE TECHNOLOGICAL CHARACTERISTICS:

Technical Characteristics Similarities
Same inspection modes
Same scan methods
Similar data display
Similar inspection probes
Similar image display functions