SEP 3 1996

K962377

SKILL TECHNOLOGIES, INC.

Innovative Biomechanics & Motion Capture Systems

1202 E. Maryland Ave., Suite 1G Phoenix, Arizona 85014 USA Telephone (602) 277-7678 & Fax: (602) 277-2326

10 June, 1996

This is a summary of safety and effectiveness information included in the 510(k) Premarket Notification for the 3D-SPINE.

REGULATORY AUTHORITY:	Safe Medical Devices Act of 1990, 21 CFR 807.92
COMPANY NAME:	Skill Technologies,Inc. 1202 E. Maryland Ave., Suite 1G Phoenix, Arizona 85014 USA Telephone (602) 277-7678 & Fax: (602) 277-2326
COMPANY CONTACT:	Stephen Cheetham Sales and Marketing Manager
ESTABLISHMENT REGISTRATION NUMBER:	[00000000]
DEVICE NAME:	3D-SPINE A REAL-TIME 3D MOTION ANALYSIS SYSTEM FOR THE Spine
TRADE NAME:	3D-SPINE
COMMON NAME:	Motion Analysis System (3D Dynamic Range-Of-Motion, ROM)
CLASSIFICATION NAME:	Spine Motion Analyzer. (Medical Device, Medical Examination, AC Powered)
CLASSIFICATION CODE:	~~80KZF~~ 87 KQX
SUBSTANTIALLY EQUIVALENT DEVICES:	1. Orthopedic Systems Inc.'s CA-6000 Spine Motion Analyzer 2. Heustis Machine Inc.'s CP-2000 Compu-Plotter

DESCRIPTION OF DEVICE:

3D-SPINE™ has been developed by Skill Technologies, Inc. as a motion measuring device. 3D-SPINE™ is a real-time three-dimensional motion analysis system that tracks, quantifies, displays and documents the motion of the spine, dynamically, accurately, instantaneously and in three-dimensions. The dynamic tests performed are; extension/flexion, lateral bending and rotation, of the cervical, thoracic, thoracolumbar and lumbar spine.

It has been designed to measure and monitor the three-dimensional angular movement of the human spine. It uses a transmitter to set up a low frequency electromagnetic field, up to a radius of 5 feet from the transmitter. Passive receivers, when brought into range of the transmitter will detect the orientation of the field and the field strength. The receivers will then report x, y and z coordinates, and pitch, yaw and roll angles at a rate of 60 samples per second to a PC computer. The computer then displays the information in the form of 3D models of the head and spine and the angular data in the form of graphs

and tables.

CONTRAINDICATIONS AND CAUTIONS. The patient being tested should have no metal fittings, plate, braces or pins, whether cutaneous or subcutaneous. These could affect the measurements. Additional warnings can be found in the Users Manual and the MCU Label attached to the top of the MCU.

INTENDED USE OF DEVICE:

3D-SPINE has the same intended use as a predicate device called the CA-6000 Spine Motion Analyzer. 3D-SPINE however, uses a different technological methodology to achieve the same results as the CA-6000. The technology used in the 3D-SPINE is the same as that used in a second predicate device called the CP-2000 Compu-Plotter, a 3D contour plotting and data gathering device. 3D-SPINE combines and produces the desired indications of the CA-6000 by using the superior features of the electromagnetic tracking principle used in the CP-2000.

SYSTEM ELEMENTS:

3D-SPINE (2 Sensor) Hardware Module Includes; Motion Capture Unit Includes; One Transmitter, One Passive 6DOF Receiver/Sensor, Additional Passive 6DOF Sensor, Adjustable Transmitter Support Stand, Adhesive Tape - Packet (Sensor Unit Attachment Tape), Head Sensor Support Strap, User's Manual, PC Computer - Pentium, 100MHz. (Minimum.), Isolation Transformer -- Medical Grade, and Color Ink Jet Printer.

The following items need assembly; The Transmitter Support Stand, the MCU transmitter must be attached to the Transmitter Support Stand, the sensors must be attached to the MCU and the MCU must be attached to the PC computer. Both the PC computer and the MCU must be plugged in to the Isolation transformer. These assembly steps plus diagrams are listed in the Users Manual. The Adhesive Tape and the Head Sensor Support Strap must be attached to the patient when testing.

INSTRUMENTATION:

There are no system specific special or standard industry instruments necessary for proper use of this device

PACKAGING:

Each 3D-SPINE system will be shipped in 6 boxes;

BOX	ITEM	PACKAGING
1	PC computer	Original Manufacturers Box
2	Monitor	Original Manufacturers Box
3	MCU (including the transmitter and sensors)	Original Manufacturers Box
4	Color Ink Jet Printer	Original Manufacturers Box
5	Transmitter Stand poles	Skill Technologies, Inc. Custom Tube
6	Transmitter Support Stand base and transmitter plate and Users Manual	Skill Technologies, Inc. Custom Box

The items shipped in the original boxes follow the industry standard of shipping computer items. The 3D-SPINE custom tube and box provide sufficient size and packing to prevent damage during shipping.

STERILIZATION/RE-STERILIZATION:

There is no sterilization or re-sterilization necessary for this device.

TESTING:

All software was tested at unit levels, incremental integration levels and operational levels. The design of the 3D-SPINE is to test the dynamic range of motion of the Cervical, Lumbar, Thoracic and Thoracolumbar spine. Test procedures and requirements were defined using the AMA guidelines as outlined in the American Medical Association -- Guides to the Evaluation of Permanent Impairment, Version 4.0 guide. The document, "Validation of the 3D-SPINE Motion Analysis System for the Spine" confirmed that the system produces reliable and accurate measurements of the orientation of the head during three cervical spine tests. The calculation methodologies used in the 3D-SPINE system are provided and verified.

EQUIVALENCE:

Skill Technologies, Inc's 3D-SPINE System is a combination of two currently marketed predicate devices:

1. CA-6000 Spine Motion Analyzer with EMG -- Computerized Anatometry Series

The following table summarizes the 3D-SPINE system compared to the CA-6000 Spine Motion Analyzer.

PARAMETERS	3D-SPINE	CA-6000	SUBSTANTIAL EQUIV.
6 Degrees of freedom of testing for the spine.	Yes	Yes	Yes
Provides Real-time data acquisition	Yes	Yes	Yes
Range of Motion (ROM) tests (Cervical, Lumbar, and Thoracic).	Yes	Yes	Yes
Real time display of motion as it occurs.	Yes	Yes	Yes
Provides progressive testing data for patients.	Yes	Yes	Yes
Compares test results to the AMA ROM Guidelines.	Yes	Yes	Yes
Data stored in ASCII format for ease of export.	Yes	Yes	Yes
Software driven.	Yes	Yes	Yes
Custom reports containing text, tables and graphs.	Yes	No	Yes
Standard reports containing text, tables and graphs.	Yes	Yes	Yes
Calculates acceleration	No	Yes	N/A
Calculates velocity	No	Yes	N/A
Provides EMG tracking during testing	No	Yes	N/A
Follows AMA Range-of-Motion Standards	Yes	Yes	Yes

The OSI CA-6000 Spine Motion Analyzer is constructed of two interconnected mechanical linkages, joined together at a vertex. The CA-6000 uses head and body harnesses to attach the ends of each of the two mechanical linkages to the head and spine, respectively. Located at the vertex is an electro-mechanical potentiometer. When the subject wearing the device moves the potentiometer detects the physical change in the angle between the two rigid arms and converts it into an electric current. The amount of current generated by the potentiometer determines the angular change that has taken place.

The 3D-SPINE requires that a small passive receiver/sensor be attached to the forehead, using a neoprene head strap, and a second sensor attached at other specified spinal locations, using double-sided adhesive tape. The relative motion of the two sensors, as detected by the change in the field strength and orientation of the magnetic field lines, is compared and the resulting angular changes recorded.

adhered to throughout the entire phase of development. These procedure helped to assure that the 3D-SPINE is as safe and effective and substantially equivalent to the CA-6000 Spine Motion Analyzer and the CP-2000 Compu-Plotter. Quality assurance procedures will be continued and maintained with the distribution of the 3D-SPINE.

The 3D-SPINE meets the following standards; UL, ACGIH, AAMI, NFPA.

Stephen Cheetham

Date: 14, June 1996

Stephen Cheetham
Sales and Marketing Manager