

APR - 3 1996

### 510(k) Summary ACE System

#### 1.0 Date Prepared

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#### 2.0 Submitter (Contact)

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#### 3.0 Device Name

Proprietary Name: ACE System  
Common Name: Electric Surgical Drill System  
Classification Name: ENT electric or pneumatic surgical drill AND  
ENT bur

#### 4.0 Device Classification

Currently marketed products of this type have been classified by the Ear, Nose and Throat Panel as follows:

ENT electric or pneumatic surgical drill	77ERL	Class II	874.4250
ENT bur	77EQJ	Class I*	874.4140

\*ENT burs have been exempted from premarket notification.

#### 5.0 Device Description

The ACE System is made up of a console, electric motor handpiece, foot pedal and various accessories. The Console is designed to mount onto an IV pole or to set on a cart and provides control of various functions such as handpiece speed and direction and irrigation. It has the ability to operate one or two handpieces (one selected at a time), angled and straight, and incorporates irrigation capability.

#### 6.0 Intended Use

The ACE System is primarily intended for the controlled incision or removal of bone in the ear, nose, throat and other areas of the head and neck. It also has applications in neurosurgery (e.g. cervical laminectomies), hand surgery, and plastic surgery (e.g. facial and mandibular reconstruction)

## 7.0 Substantial Equivalence

The new ACE System is substantially equivalent to the following currently marketed surgical drills in that it has the same intended use (controlled incision of bone) and equivalent features (irrigation, handpiece styles, etc.) and performance characteristics (speed and torque):

<u>DEVICE</u>	<u>Manufacturer</u>	<u>510K Number</u>
Micro-Craft® Power System	Xomed	K791407
Synergy™	Smith & Nephew - Richards	unknown
Jedmed Otologic Drill	Bien-Aire (Marketed by Jedmed)	unknown
UltraPower™ Complete Drill System	Hall Surgical / Zimmer	unknown
Bone Dissecting System	Med <sup>next</sup>	K926547

## 7.1 Discussion of Differences

There are no substantial differences between the ACE System and the equivalent electrical drill systems other than in device performance, as noted by the enhanced speed and torque with the ACE System. The improved performance of the ACE System is equivalent to the performance of pneumatic drills currently on the market. The ACE System combines the speed and torque of the equivalent Pneumatic drills with the design and controls of the equivalent electrical systems.