

**STAR DENTAL HIGH SPEED HANDPIECE**

**510(k) Summary**

K960719

**Company:**

Star Dental, Division of Den-Tal-Ez, Inc.  
Owner/operator number 2520265

K960719

**Contact Person:**

MAR 28 1996

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**Device Trade Name:**

430 Series High Speed Handpiece

**Common or Usual Name:**

High Speed Handpiece

**Predicate Device:**

Star Dental 430 Series High Speed Handpiece

**Intended Use/Description:**

High speed dental handpieces are used intraorally by trained dental professionals for drilling and preparation of dental cavities for restoration, such as fillings. The intended use of the device is identical to that of the predicate. The technology, design, manufacturing, and materials are substantially equivalent to those of other handpieces on the market, including that of the current 430 series handpiece.

**Substantial Equivalence:**

The determination of substantial equivalence is based on the fact that the proposed Star Dental device and the predicate Star Dental device utilize substantially equivalent intended use, technology, design, manufacturing, and materials and so will be substantially equivalent in clinical performance.