

**Premarket Approval (PMA) Package for**  
**Dockets Management Branch**

SEP 28 09:34

**PMA Number P930016/S021**  
**Docket # 2005M-0382**

**VISX, Inc.**  
**STAR S4 IR™ Excimer Laser System with**  
**Variable Spot Scanning (VSS™)**  
**and WaveScan WaveFront® System**

**Includes:**

**Approval Order**  
**Summary of Safety and Effectiveness Data (SSED)**  
**Labeling**

2005M-0382

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