AUG 22 [redacted]

510k Summary

K961122

Device Name:

Classification Name:	Surgical Knife, 79 EMF, Class I Surgical Instrument Light, 79 FSQ, Class II
Common/Usual Name:	Lighted Knife
Proprietary Name:	Stryker Knifelight

Device Sponsor:

Stryker Corporation
Instruments Division
4100 East Milham Avenue
Kalamazoo, MI 49001
Registration No: 1811755

Regulatory Class: Class II

Summary of Safety and Effectiveness:

The Stryker Knifelight is a manual surgical instrument used for the release of ligaments or other tissue including, but not limited to, the carpal tunnel ligament. It features an integrated light source to illuminate the surgical site. The Stryker Knifelight allows for a minimally open technique with minimal disturbance of surrounding tissue.

The Stryker Knifelight is a sterile, single use, completely disposable ligament and tissue release knife with an integrated light source. The light source is intended to provide improved visualization of tissues and ligaments inside areas with restricted view due to small incisions. During minimally open carpal ligament surgical release, this device will improve visualization of the carpal ligament, median nerve and functional ligaments and tendons. Additionally, the surgical blade has integral protective retractors which provide for additional protection of the surrounding tissue during surgery. A standard elevator may be available with the device to facilitate ligament or tissue division.

The Stryker Knifelight is equivalent to existing marketed products by companies such as Biomet and Medtronic. Intended use, function, and safety risks are all substantially equivalent.

The Stryker Knifelight does not raise any new safety and efficacy concerns when compared to similar legally marketed devices. Therefore, the Stryker Knifelight is substantially equivalent to these existing devices.

Diane Davis

Diane Davis
Regulatory Affairs Representative
Stryker Instruments