

AUG - 5 1996

K962022

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
POWERCUT® GOLD SURGICAL POWER SYSTEM****Appendix G**

Manufacturer: Dagmar, Incorporated
5733 S. Laburnum Avenue
Richmond, Virginia 23231

Regulatory Affairs Contact: Maryalice Smith
Surgical Group
1500 Waukegan Road MPK
McGaw Park, IL

Telephone: (847) 785-3322

Date Summary Prepared: May 1996

Common Name: Modified PowerCut® Gold
Surgical System

Classification: Class I per 21CFR § 878.4820

Predicate Device: PowerCut® Gold Battery
Powered Surgical System
(K863696)

Description: The modified PowerCut® Gold
Surgical system will be a
reusable, non-sterile, AC
powered device. It is designed
for use in arthroscopic surgical
procedures that require intra-
articular tissue resection,
shaving, and/or abrading of the
knee or shoulder joint. The
system is used in conjunction
with direct arthroscopic camera

Description:

visualization utilizing a separate port of entry (incision site). Blades and drills are available separately and are not included in this Premarket Notification.

Intended Use:

The Modified PowerCut® Gold Surgical System is designed for use in arthroscopic surgical procedures where intra-articular tissue resection, shaving, and/or abrading the knee or shoulder joint is required. The system is used in conjunction with direct arthroscopic camera visualization utilizing a separate port of entry (incision site).

Substantial Equivalence:

The Modified PowerCut® Gold Surgical System is substantially equivalent to the following commercially marketed surgical power devices:

1. V. Mueller PowerCut® Gold Surgical System K863696
2. Dyonics PS3500
3. Stryker SE3
4. Linvatec Concepts IntraArc®

Summary of Testing:

Quality performance testing is conducted on 100% of finished product systems. Torque measurements are recorded at various RPM reading to ensure that torque parameters meet those specified in the System Design Requirements. Test samples passed all acceptance criteria established in the functional protocol testing. The modified PowerCut® Gold Surgical System has been tested to meet the Electrical Safety and Thermal protection requirements of UL-544 and IEC 601. Cleaning and sterilization of this reusable device have been validated and are included within the label copy. The modified handpiece is composed of

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various medical grades of stainless steel and aluminum, and have only a brief and incidental contact with the patient. These materials have a long and well-established history of biocompatibility.