



510(k) SUMMARY

K965054

SAFETY AND EFFECTIVENESS SUMMARY

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This information of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name/Address:

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Contact Person:

Same as above

Date Summary Prepared:

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Device Name:

Common Name:	Electrosurgical Device, Cutting and Coagulation & Accessories
Trade Name:	Not yet established
Classification (if known):	Class II, Tier II, 79GEI, General and Plastic Surgery, 21 CFR 878.4400

Predicate Devices:

MegaDyne Medical Products, Inc pencils and electrodes
Valleylab pencils and electrodes
Conmed pencils and electrodes
E&M Engineering pencils

Applicant Device Description:

This device has a molded plastic housing. The mode switch selects the appropriate electrosurgical function (CUT or COAG). Exiting the housing is a ten foot cable which has a standard 3-prong plug to connect to the generator. The electrode packaged with this pencil will be either a coated electrode or a regular bare electrode, and with or without a holster. This device is a single use, disposable. It is sold sterile.

Applicant Device Intended Use:

The intended use of this device is to conduct monopolar electrosurgical energy from an electrosurgical unit (ESU) or generator, to an electrosurgical electrode and subsequently to the target tissue. The device is disposable and sold sterile.

Technological Characteristics:

This device is substantially equivalent in materials and operation to other pencils already on the market. There are no new technological characteristics and therefore no new questions of safety and effectiveness.

Performance Data:

MegaDyne voluntarily complies with ANSI/AAMI HF 18-1993