510(k) Summary

Page 1 of 2

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

A. Name, Address, Phone and Fax Number of Applicant

Primaeva Medical, Inc.
42840 Christy Street, Suite 101
Fremont, CA 94538, USA
Telephone: (510) 933-6000
Fax: (510) 933-6001

B. Contact Person

Bankim Mehta
President & CEO
Phone: (510) 933-6010
Fax: (510) 933-6001

DEC 2 6 2007

C. Date Prepared

August 8, 2007

D. Device Name

Trade Name:	*Finesse* System
Common Name:	Electrosurgical Unit and Accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Product Code GEI)

E. Predicate Devices

The Primaeva Medical *Finesse* System is substantially equivalent to the Thermage ThermaCool System (K000944 and K003183), ArthroCare Visage Cosmetic Surgery System (K981870), and Radionics Cool-Tip RF System (K984552).

F. Device Description

The Primaeva Medical *Finesse* System is comprised of four primary components; an RF Generator with User Interface Software, a Cooling System Hand Piece, a Cooler Controller, and a disposable Electrode Insertion Device with an integrated cable. RF energy is delivered from the RF Generator, through the electrodes, and into the target tissue. The bi-polar RF energy is delivered between independent adjacent electrode pairs. The RF Generator, Cooler Controller, and Cooling System Hand Piece are not

disposable. Each Electrode Insertion Device is supplied sterile and is for single patient use only and cannot be re-sterilized.

The insertion device is a hand-held mechanical device that is used to insert the electrodes, at an acute angle, into the target tissue. The device has ten (10) electrodes arranged in a single row array. The device has a mechanism to deploy and retract the electrodes when actuated by the user. There is a cable with a connector that connects to the RF Generator.

The Cooler system comprises a solid state cooling device with a feedback loop to monitor and control temperature. The cooling device is placed on the tissue surface during the treatment cycle.

The RF Generator is the energy source for the system. Accessory cables and power cords are also supplied with the system.

G. Intended Use

The Primaeva Medical *Finesse* System is intended for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.

H. Technological Comparison

The technological characteristics and principals of operation of the *Finesse* System are substantially equivalent to the noted predicate devices.

I. Summary of Pre-Clinical Data

Results of pre-clinical testing demonstrated that the *Finesse* System is safe and effective for its intended use.

J. Summary of Data

The *Finesse* System has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, pre-clinical testing was conducted to validate the performance of the device and ensure the *Finesse* System functions as intended and meets design specifications. The comparison and pre-clinical results demonstrate that the device is substantially equivalent to the predicate devices and is safe and effective in its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2008

Primaeva Medical, Inc.
% Mr. Brian Grigsby
VP, QA & RA
42840 Christy Street, Suite 101
Fremont, California 94538

Re: K072261
Trade/Device Name: Finesse System
Regulatory Number: 21 CFR 878.4400
Regulatory Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 11, 2007
Received: December 13, 2007

Dear Mr. Grigsby:

This letter corrects our substantially equivalent letter of December 26, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K 072261

Device Name: Finesse System

Indications for Use:

The Primaeva Medical Finesse System is indicated for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.

Prescription Use ✓ **OR** **Over-The-Counter Use** _____

(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bue M.D.

(Division Sign-Off)
Division of General, Restorati
and Neurological Devices

510(k) Number K072261