Ms. Judith E. O'Grady, R.N., M.S.N.
Vice President, Regulatory Affairs
Integra LifeSciences Corporation
P.O. Box 688
Plainsboro, New Jersey 08536

Re: P900033
INTEGRA® Artificial Skin
Filed: April 11, 1995
Amended: July 3, September 17, November 30, 1990;
January 29, April 26, August 22, August 26, December
23, 1991; January 10, February 20, March 30, August 14,
1992; January 28, March 8, October 4, November 19, 24,
and December 22, 1993; January 28, March 29, April 12,
August 29, and December 22, 1994; February 1, June 15,
August 3, 1995; and February 8, 1996.

Dear Ms. O'Grady:

The Center for Devices and Radiological Health (CDRH) of the
Food and Drug Administration (FDA) has completed its review of
your premarket approval application (PMA) for the Integra
Artificial Skin. This device is indicated for the post-
excisional treatment of life-threatening full-thickness or
deep partial-thickness thermal injury where sufficient
autograft is not available at the time of excision or not
desirable due to the physiological condition of the patient.
We are pleased to inform you that the PMA is approved subject
to the conditions described below and in the "Conditions of
Approval" (enclosed). You may begin commercial distribution
of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted
to prescription use in accordance with 21 CFR 801.109 within
the meaning of section 520(e) of the Federal Food, Drug, and
Cosmetic Act (the act) under the authority of section
515(d)(1)(B)(ii) of the act. FDA has also determined that to
ensure the safe and effective use of the device that the
device is further restricted within the meaning of section
520(e) under the authority of section 515(d)(1)(B)(ii), (1)
insofar as the labeling specify the requirements that apply to
the training of practitioners who may use the device as
approved in this order and (2) insofar as the sale,
distribution, and use must not violate sections 502(q) and (r)
of the act.
Expiration dating for this device has been established and approved at 1 year, to be stored flat under refrigeration at 35–46°F (2–5°C), protected from freezing.

In addition to the postapproval requirements in the enclosure, the postapproval reports must include the information from a post-approval study for a series of 200 patients, at 6 investigational sites (please note, a minimum of 20 patients per site is advised). Patient data is to be collected and a report generated and submitted annually to FDA for review. This report should include a summary of adverse events, morbidity, and mortality statistics, analysis of the incidence of systemic infection associated with device use, and analysis of whether there is an association between systemic infection and mortality due to device use.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that as soon as possible, and before commercial distribution of your device, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard Drive
Rockville, Maryland 20850
If you have any questions concerning this approval order, please contact Ms. Frances Moreland-Curtis at (301) 594-3090.

Sincerely yours,

Susan Alpert, Ph.D., M.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure