SUMMARY REVIEW MEMO TEMPLATE

DATE: **OCTOBER 31, 2011**

FROM: [redacted]

SUBJECT: **P050037/S24, RADIESSE**

CONTACT: **MS. KRISTI RESELE**

TO: **THE RECORD**

BACKGROUND/ REASON FOR SUPPLEMENT

P050037/24 is a 180 Day Supplement that requested approval of a new product fill volume. In specific, the introduction of a 3.0 cc fill volume syringe with a curved handle to the existing line of products (i.e., 0.3, 0.8 and 1.3 cc fill volumes with a straight handle and a 1.5 cc fill volume in a syringe with a curved handle) was requested. The intended use/indications for use for Radiesse will remain the same.

REVIEW TEAM

Table 1 below lists the participants in this review team and their role in the review of the supplement:

Reviewer	Role
[redacted] CDRH/ODE/DSORD	Lead Reviewer
[redacted] Information Analysis Branch/CDRH/OSB/DPS	Post Market MAUDE Reviewer

Table 1: Review team for P050037/s024

INDICATIONS FOR USE

The device is approved for: 1) for subdermal implantation for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus (PMA P050037) and 2) subdermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds (PMA P050052).

DEVICE DESCRIPTION

Radiesse is comprised of Calcium Hydroxylapatite, USP Grade Sodium Carboxymethylcellulose, USP Grade Glycerin and USP Grade Sterile Water for Injection.

PRECLINICAL/BENCH

Manufacturing Information

This supplement included information on the manufacturing steps and sterilization procedures that were revised for production of a 3.0 cc volume syringe. Qualification information was reviewed for new steps for this new fill size and re-review of the data submitted in the original PMA was performed for steps that remained unchanged.

Stability Data

Real time and accelerated data concerning changes in (b) (4) were submitted in support of the proposed 6 month expiration date for the 3.0 cc fill volume syringe. In addition, information concerning the maintenance of package integrity was provided to document the continued sterility and (b) (4) nature of the product. This information, in combination with the data submitted in the original PMA, were sufficient to support the proposed expiration date.

Clinical Data

The original PMA provided sufficient clinical data to support approval of the new 3.0cc syringe volume. To further evaluate the Post Marketing performance of Radiesse, FDA evaluated the incidence and types of Medical Device Reports found in the Manufacturer and User Facility Device Experience database. This information confirmed that approval of a 3.0 cc volume syringe would be appropriate.

Labeling Review

A review of the product label was performed to insure that the appropriate syringe volume sizes and corresponding syringe needle sizes were presented in the package insert.

CONCLUSION

Based on the data presented in the supplement, requested to introduce a 3.0 cc fill volume Radiesse syringe with a curved handle to the existing line of products should be approved.

RECOMMENDATION - I recommend that the supplement be **Approved**.

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Reviewer name Date

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Name, Chief, Branch Date