



# Brief Summary of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee

## Meeting – February 27, 2015

### Introduction:

On February 27, 2015, the Panel discussed, made recommendations, and voted on information regarding the premarket approval application (PMA) for the Radiesse® Dermal Filler device sponsored by Merz North America, Inc. The proposed indication for use for Radiesse®, as stated in the PMA, is as follows: The Radiesse® device is for subdermal implantation for hand augmentation to correct volume deficit in the hands. The FDA has previously approved the Radiesse® device for the following two indications for use: The Radiesse® device is indicated for subdermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds. The Radiesse® device is also indicated for subdermal implantation for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus.

### Panel Deliberations/FDA Questions:

The panel generally agreed that the adverse events (AEs) observed in the clinical study were expected and overall Radiesse® was considered to be safe since no serious AEs were reported and the majority of the AEs were mainly mild to moderate in nature which required little intervention.

The panel raised concerns about who can administer Radiesse® in the hands and discussed specific patient populations that should not be injected with Radiesse® in the hand. The panel agreed that the indications should be specified for the dorsum of the hand. The panel also agreed the labeling should identify the types of physicians that can administer the device as well as include a clear list of precautions, contraindications, and warnings in the labeling. The panel agreed Radiesse® should not be used in patients that have very severe loss of fatty tissue; i.e., marked visibility of veins and tendons (4 on the Merz Hand Grading Scale (MHGS)). The panel noted these types of patients will most likely require larger volumes of Radiesse® than was administered in the clinical study and therefore further investigation is needed to evaluate the adverse event profile.

The panel noted the data collected to evaluate potential effects on hand function of the Radiesse® injection were difficult to interpret. The panel agreed the data captured for the hand function testing performed was variable and was not adequate to understand how hand function is affected after Radiesse® injection. The panel agreed that hand function testing needs to be further studied.

The panel expressed concerns about the radiopaque properties of Radiesse®, and the absence of data that evaluated the potential impact of Radiesse® on hand imaging. The panel agreed that both short-term and long-term studies should be performed to assess hand imaging post-injection of Radiesse® into the dorsum of the hand.

The panel discussed the effectiveness of Radiesse® using the MHGS scale with live masked evaluators. Although, the primary effectiveness endpoint was met, the panel noted significant variability, with one site having 68% (25/37) of patients with greater than a 2 point improvement compared to all other sites showing 8% (6/76) of subjects showing 2 point improvement. The panel agreed that variability was observed between sites in regards to the amount of improvement. The panel discussed whether an independent assessment of the patient photographs would provide valuable information to the Agency regarding the variability. The panel concurred that the variability may be due to inconsistent use of the MHGS and/or injector technique. However, the panel generally agreed that Radiesse® was effective when comparing treatment versus control groups.

The panel concluded that additional studies are needed to: (1) assess the effect of Radiesse® injection on hand function, (2) evaluate how Radiesse® impacts hand imaging and (3) assess effects of Radiesse® when used in patients with severity of 4 on the MHGS.

### **Open Public Hearing:**

Multiple public speakers attended the panel meeting in support of the Radiesse® device. However, one patient who received the Radiesse® device for facial implantation gave a detailed adverse account on the Radiesse® device itself. She stated she endured a bio-film infection from the device itself which was later recalled; she added that the device couldn't be completely removed and she continues to experience medical issues. The panel determined that this type of occurrence is rare.

### **Panel Vote Results:**

**Question 1:** Is there reasonable assurance that the Radiesse® device is safe for the proposed indications for use; the panelists voted:

11 Favorable  
0 Abstained  
3 Contrary

**Question 2:** Is there reasonable assurance that the Radiesse® device is effective for the proposed indications for use, the panelists voted:

12 Favorable  
0 Abstained  
2 Contrary

**Question 3:** Does the benefits outweigh the risks for the A Radiesse® device in patients who meet the criteria specified in the proposed indication, the panelists voted:

9 Favorable  
1 Abstained  
4 Contrary

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