



CONVERSATION RECORD

6/18/18

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

J. Rakowski (RSO), Mara Jelisch (management)

DATE OF CONTACT

06/18/2018

TYPE OF CONVERSATION

E-MAIL

TELEPHONE

INCOMING

OUTGOING

E-MAIL ADDRESS

rakowski@karmanos.org

TELEPHONE NUMBER

(313) 576-9555

ORGANIZATION

Karmanos Cancer Center

DOCKET NUMBER(S)

030-09376

LICENSE NUMBER(S)

24-04127-06

CONTROL NUMBER(S)

602771

SUBJECT

Authorization as requested in letters dated 3/28/18 (ML18089A253) and 5/9/18 (ML18135A189)

SUMMARY

On 6/18/18 Magdalena Gryglak, Patty Pelke, Joe Rakowski, Mara Jelisch discussed details pertaining to the use of the new device. Specifically, the staff discussed the authorization for Dr. Dominello and details of what pre-operational testing of the new device entails. During the discussion, reviewer learned that the proposed facility has not been constructed yet. Due to many factors associated with construction and details pertaining to the design of the facility, parties agreed that the licensee is not ready to receive the new device. As a result, the licensee agreed to withdraw its request to license the new device at this time.

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ACTION REQUIRED (IF ANY)

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NAME OF PERSON DOCUMENTING CONVERSATION

Magdalena R. Gryglak

SIGNATURE

Magdalena Gryglak