IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

UNITED STATES OF AMERICA	)	
	)	
Plaintiff,	)	
	)	
v.	)	No: 25-cr-20032
	)	
SANJEEV KUMAR,	)	
	)	
Defendant.	)	

SUPPLEMENTAL MOTION FOR A NEW TRIAL UNDER FEDERAL RULE OF CRIMINAL PROCEDURE 33

COMES NOW, Sanjeev Kumar through his counsel and supplements his previously filed motion for a new trial (ECF 287), based upon newly discovered evidence obtained from the Food and Drug Administration (FDA) showing that the Government presented false and misleading facts, contrary to FDA rules, to obtain convictions against Dr. Kumar on Counts 33 and 35 for adulteration of hysteroscopes cleared for reprocessing.

The Government presented the expert testimony Dr. Poulomi Nandy that an Olympus HYF-HP hysterofiberscope (hereinafter "Olympus scope") requires sterilization and that high level disinfection is insufficient to reprocess the device, based on the assertion that the 510(k) clearance for the Olympus scope did not cover high level disinfection as a permissible reprocessing method. Dr. Nandy thus rejected the "high-level disinfecting" reprocessing procedures set forth in the Instructions for Use manual ("IFU") for the Olympus scope and testified repeatedly that "sterilization" was the only reprocessing procedure accepted by the FDA for this device.

The FDA Division of Industry and Consumer Education (DICE), the Center for Device and Radiological Health (CDRH) has verified that providers, like Dr. Kumar, should refer to a device's IFU, rather than the device's 510(k) letter, for the appropriate and applicable reprocessing instructions. (See FDA Guidance, attached hereto as **Exhibit A and Exhibit B**.) The Olympus IFU provides that a physician can use high level disinfectant to reprocess the Olympus scopes. The FDA's directive is directly opposite of the Government's position at trial that the Olympus scope was only properly reprocessed if it underwent sterilization. Dr. Nandy's false and misleading testimony further buttressed the government's argument that Dr. Kumar was a bad doctor that did not follow appropriate medical procedures – supporting his convictions on all counts.

The Government knew the position was wrong or, to a minimum, should have known that Dr. Nandy's testimony on a central part of their case was false and misleading or that the Government needed to investigate her position more fully. Based upon the extreme prejudice caused by Dr. Nandy's false testimony, Dr. Kumar is entitled to a new trial as dictated by Rule 33 of the Federal Rules of Criminal Procedure. *See* Fed. R. Crim. P. 33(a).

FACTS

Starting with its opening argument, the Government emphasized to the jury that the Olympus scopes charged in Counts 33 through 36 needed to be "sterilized" for reprocessing.

> Now, Counts 33 through 36 are related to devices that are cleared for reprocessing. So what does that mean? Well, reprocessing, some devices can be cleared for that. They can be reprocessed, re-sterilized. Okay. So this is a uterus, a procedure that has to go into the uterus. It has to be sterile. Sterile means sterile. There is a whole industry of sterilization that the Food and Drug Administration also regulates that can do that, they can sterilize. There was no way at Poplar Avenue Clinic to sterilize any of these reusable devices. And the Olympus HYF Hysteroscope was cleared for reprocessing and it was cleared to be resterilized and reused, but that's not what was happening at Poplar Avenue Clinic.

(Government's Opening Statement, PageID 8013 at 1–14.)

Dr. Nandy, an employee of the FDA, repeatedly supported the Government's false and misleading position throughout her testimony. Dr. Nandy gave expert testimony that Olympus scopes could not be reprocessed by High Level Disinfection methods:

> [F]or both diagnostic as well as operative hysteroscopes, depending on the fact that they're entering the uterus, we would hold them to the same level of reprocessing as for a critical device. Even though it is not being used for operative procedures, they were not cleared for high level disinfection. They were only cleared for sterilization.

(Testimony of Poloumi Nand, PageID 3796 at 4–10.)

In entering a "sterile" cavity Dr. Nandy testified that Olympus scopes must be "sterilized":

> When [the FDA] originally cleared these devices, they were cleared for high level disinfection followed by sterilization. High level disinfection was not a mandatory step, but the sponsor chose to conduct that because they were already doing that for other scopes in the product family which were not hysteroscopes. But the hysteroscopes were ultimately cleared with sterilization.

(*Id*. at PageID 3803, 16–24.)

In explaining her opinion that sterilization was required, Dr. Nandy emphasized that diagnostic scopes used in the uterus were considered a critical device that required sterilization:

> [D]epending on where [endoscopes] are used, their categorization is going to change. So for example, hysteroscopes which are used to perform diagnostic or surgical procedures in the uterus would be considered a critical device because they're going into the uterus.

(*Id.* at PageID 3738, 4–9.)

As to the Olympus Scopes used at PAC, Dr. Nandy misleadingly testified that the Olympus Scopes required "sterilization" and could not be reprocessed using high level disinfection.

> "*It's important to make sure that I communicate that FDA has not cleared any hysteroscopes with high level disinfection. All hysteroscopes, including this very old device from Olympus, was cleared with sterilization.*

(*Id*. at PageID 3810, 18–21(emphasis added).)

Dr. Nandy described in detail the procedures that needed to be used to "sterilize" the Olympus HYF-XP was only cleared for reprocessing using "ethylene oxide." (*Id.* at PageID3781, 1-9) *Dr.* Nandy underscored that this method of sterilization could not be done in an OB/GYN office such as the Poplar Avenue Clinic as the cleaning device is large and required specialization. *Id*. at PageId 3781, 1-9). Dr. Nandy throughout her testimony left the mistaken conclusion that scopes entering the uterus needed "sterilization." Even at sidebar the government clearly pressed their mistaken and prejudicial position that the FDA required "sterilization" for the reprocessing of the Olympus scopes.

> "we had the authority come in, the FDA lead reviewer in their expert, the Olympus not any hysteroscope that is re-used has never – the FDA never cleared any hysteroscopes for high level disinfection. It is only cleared for sterilization

(Crum PageID 7540, 7-14)

In closing the government argued to the jury that "sterilization" was required and the failure to sterilize the Olympus Scopes at PAC left the scopes "adulterated." The government stressed that the adulteration went directly to their deliberations on counts 33 through 36.

> Now, a very interesting witness, I thought, was Dr. Poulomi Nandy. She was the lead reviewer. She's the microbiologist from the FDA. And she explained that these devices that enter the uterus must be sterile, that in fact the FDA has never cleared a reprocessable or any hysteroscope as anything other than as a sterile device, as a critical device that must be sterile.

(Government's closing PageID 7380, 12-18)

The IFU submitted in this case provided the Olympus Scopes could be reprocessed either by "sterilization" or by "high level disinfection." (Trial Exhibit TR 57) The Government consistently argued, and elicited testimony from Dr. Nandy, that providers cannot rely on a device's IFU to determine how to reprocess a device.

The Olympus Scope's IFU clearly provides that the scopes could be reprocessed either by "high level disinfection" or "sterilization." The FDA recognizes the IFU as the leading document that is to be followed by physicians in their medical practice. The FDA's Division of Industry and Consumer Education at the Center for Devices and Radiological Health (CDRH) stated a doctor should follow the procedures provided in the device's IFU. The IFU is the document recognized by the FDA that ensures safety and effectiveness of unresolvable conflict, the device IFU takes precedence. (Attachment A and Attachment B)

LAW AND ARGUMENT

From the inception of this case, starting with the indictment, the Government has taken the position that the FDA required sterilization for the Olympus Scopes used at PAC and that physicians must defer to the 510(k) clearance for a medical device, not the device's IFU. As the Government puts it, the lack of sterilization by PAC made the multi-use scopes adulterated and therefore constituted a crime. During trial, the Government's expert, Dr. Nandy, supported their position and erroneously stated that FDA guidance mandated "sterilization" of the Olympus Scopes and that physicians cannot rely on a medical device's IFU for clearing instructions but must defer to the 510k letter. Now the FDA has proven that the government's position of "sterilizations" was wrong. The Olympus Scopes could be reprocessed using high level disinfectant- the procedure used at PAC to reprocess their Olympus scopes.

At a bare minimum, the Government should have known that the FDA directs end users to follow the IFU. However, the Government was wrong in their position that the FDA required sterilization. The Government wrongfully charged Dr. Kumar on the debunked theory that Olympus Scopes could not be reprocessed as directed by the IFU. This clearly prejudiced Dr. Kumar both in the jury deliberations of counts 33 and 35 as well as supporting the government's

overarching story that Dr. Kumar was a bad doctor that knowingly failed to follow the Government's rules and regulations. The only remedy for the Government's gross error is to grant a new trial.

Generally, motions for a new trial based on newly discovered evidence are disfavored and should be granted with caution. *United States v. Seage*, 930 F.2d 482, 488 (6th Cir. 1991). However, when it is shown that the Government's case includes false testimony that the prosecution knew or should have known was false, a new trial must be held if there is any reasonable likelihood that the falsity effected the outcome. *United States v. Stoddard*, 875 F.2d 1233, 1237-38 (6th Cir. 1989). In *Stoddard*, the bank's membership in the federal reserve system was an essential element of the offense, newly discovered evidence of non-membership, although available earlier with defendant's due diligence required new trial due to prosecutor's gross lack of diligence.

As in *Stoddard*, the Government's due diligence should have shown that Dr. Nandy's testimony requiring "sterilization" for the Olympus Scope at PAC was wrong and had no evidentiary value in the charges of adulteration. The Government's due diligence should have revealed that the IFU was a legal document that directed physicians in the reprocessing of Olympus Scopes. This information is within the very agency that worked for more than three years in bringing the charges against Dr. Kumar.

The Government's position throughout the trial was that the multi-use scopes were sterile and required special reprocessing before re-use. In the case of Poplar Avenue Clinic, the procedures for reprocessing the multi-use scopes did not require "sterilization" as testified by Dr. Nandy. Without the Government's erroneous reliance on a non-existent FDA" rule of "sterilization," there is no basis to support the convictions against Dr. Kumar on Counts 33 and 35. Those scopes were reprocessed by high level disinfectant that was connected to the tower to which the multi-use

scopes were attached. In addition, PAC used washers to provide additional reprocessing of the Olympus scopes. While using the scope washer was not required, PAC purchased the scope-washers as an additional means of providing additional cleaning. Moreover, the negative spillover effect caused by the erroneous government factual and legal conclusions is clear. The government wrongfully used false and misleading fact of sterilization to further their now debunked argument that Dr. Kumar used adulterated multi-use devices. The prejudice is overwhelming and clearly prevented Dr. Kumar from receiving the "fair" trial to which he was entitled.

CONCLUSION

The Government was grossly negligent and reckless in their failure to recognize their wrong position concerning the reprocessing of the Olympus scopes. The Government was in a unique position to recognize their gross factual error but failed to do so. These gross errors can only be remedied by a new trial. The Government's presentation of false and misleading evidence prevented Dr. Kumar from receiving a "fair" trial, which can only be corrected by a new trial.

Respectfully submitted,

s/ Brian Daniel Mounce
Lawrence J. Laurenzi (TN BPR No. 9529)
Brian Daniel Mounce (TN BPR No. 39545)
Elena R. Mosby (TN BPR No. 40562)
BURCH, PORTER & JOHNSON, PLLC
130 N. Court Ave.
Memphis, TN 38103
(901) 525-5000

Ronald Chapman, III (pro hac vice)
CHAPMAN LAW GROUP
1441 W. Long Lake Rd., Ste. 310
Troy, Michigan 48098
(248) 644-6323

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the forgoing was forward by electronic means via the Court's electronic filing system to all parties to this matter this April, 7, 2026.

s/ Brian Daniel Mounce

CERTIFICATE OF CONSULTATION

The undersigned counsel for Dr. Sanjeev Kumar hereby states that he consulted with counsel for the Government, Lynn Crum, on both Thursday April 2, 2026, and Saturday, April 4, 2026. The Government opposes Dr. Kumar's motion and thus the Parties are unable to reach an agreement as to all issues herein.

s/ Lawrence J. Laurenzi
and
s/ Brian Daniel Mounce

SUPPLEMENTAL MOTION FOR A NEW TRIAL

UNDER FEDERAL RULE OF CRIMINAL PROCEDURE 33

EXHIBIT A

Gmail Sanjeev kumar <sanje45@gmail.com>

Support at FDA/DICE Re:Re: Support at FDA/DICE Re:question re product IFU - 0326-00814620 - 0326-008

1 message

"DICE" <dice@fda.hhs.gov> <dice@fda.hhs.gov> Fri, Mar 20, 2026 at 11:46 AM
To: "sanje45@gmail.com" <sanje45@gmail.com>

FDA U.S. FOOD & DRUG ADMINISTRATION

Dear Sanjeev Kumar,

Thank you for contacting the Division of Industry and Consumer Education (DICE) at FDA's Center for Devices and Radiological Health (CDRH) DICE@fda.hhs.gov e-mail account.

If there is a conflict between verbal guidance from an FDA employee and the FDA-approved product Instructions for Use (IFU), a physician should follow the product's IFU. The IFU is the legally recognized, validated document ensuring safety and effectiveness, and in cases of unresolvable conflict, the device IFU takes precedence.

If you have any further questions, feel free to contact The Division of Industry and Consumer Education by email at DICE@fda.hhs.gov. I hope that this information is helpful.

Sincerely,

Consumer Education Team
Division of Industry and Consumer Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Department of Health and Human Services

Original Message
From: sanje45@gmail.com
Sent: 3/19/2026

Subject: Re: Support at FDA/DICE Re:question re product IFU - 0326-00814620
Message:

Dear FDA staff
just to clarify-
if there is conflict between a FDA employee and product IFU; a physician should choose a product IFU to follow. I am correct in interpreting your response?
thank you
sanjeev kumar MD

On Thu, Mar 19, 2026 at 12:14?PM "DICE" <dice@fda.hhs.gov> <dice@fda.hhs.gov> wrote:

> Dear Sanjeev Kumar,
>
> Thank you for contacting the Division of Industry and Consumer

Education
> (DICE) at FDA's Center for Devices and Radiological Health (CDRH)
> DICE@fda.hhs.gov e-mail account.
>
>
> In response to your inquiry regarding re product of an IFU, please refer
> to the clearance information/summary of safety and effectiveness for this
> device, including the instructions for use. You can search our database
at 510(k)
> Premarket Notification (fda.gov)
> <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
for
> the specific device you are inquiring about.
>
>
>
> Additionally, you should refer to the Instructions for Use (IFU) that
> accompanied the device and contact the manufacturer directly if needed.
>
>
>
> If you have any further questions, feel free to contact The Division of
> Industry and Consumer Education by email at DICE@fda.hhs.gov. I
hope this
> information is helpful.
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>
>
> Sincerely,
>
> Consumer Education Team
> Division of Industry and Consumer Education
> Center for Devices and Radiological Health
> U.S. Food and Drug Administration
> Department of Health and Human Services
>
> *This communication is consistent with 21 CFR 10.85 (k) and constitutes
an
> informal communication that represents my best judgment at this time
but
> does not constitute an advisory opinion, does not necessarily represent
the
> formal position of FDA, and does not bind or otherwise obligate or
commit

> the agency to the views expressed. This communication is intended for the
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> from the saved sources and notify DICE by email at:DICE@fda.hhs.gov
> <Industry.Devices@fda.gov> immediately.*
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>
> Original Message
> From: sanje45@gmail.com
> Sent: 3/18/2026
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> ---
> Subject: question re product IFU
> Message:
>
> DEAR FDA Staff
> question-
> if a FDA employee gives an instruction to reprocess a surgical device that
> conflicts with the product IFU cleared by the FDA for this particular
> device, which one should the physician believe? Product IFU or the fda
> employee?
>
> pls let me know
> tnx
> sincerely
>
> --
>
> Sanjeev Kumar, MD
> Board Certified Gynecological Oncologist & Pelvic Surgeon
>
> Gynecological Oncology & Pelvic Surgery
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> E: sanje45@gmail.com
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> C: 248-924-1791
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> 6584 Poplar Ave, Suite 400, Memphis TN, 38138

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> P: 901-300-6713 | F: 901-881-0337
>
> pac-md.com <
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Sanjeev Kumar, MD
Board Certified Gynecological Oncologist & Pelvic Surgeon, Poplar Ave Clinic, PLLC

Gynecological Oncology & Pelvic Surgery

E: sanje45@gmail.com

C: 248-924-1791

6584 Poplar Ave, Suite 400, Memphis TN, 38138

P: 901-300-6713 | F: 901-881-0337

pac-md.com <http://pac-md.com>

DEAR FDA Staff
question-
if a FDA employee gives an instruction to reprocess a surgical device that conflicts with the product IFU cleared by the FDA for this particular device, which one should the physician believe? Product IFU or the fda employee?

pls let me know
tnx
sincerely

--

Sanjeev Kumar, MD
Board Certified Gynecological Oncologist & Pelvic Surgeon

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pac-md.com <http://secure-web.cisco.com/1f3wsc4LKOpyoMGC65UFXO1KXKWUsV3RJ8TY1_ZHybir1Kf18qsIwrL6URUHl3TK3dtuFDC5Dv8PLfV5ANlq4Yc139tZaOLz9-HbmlZqSx7AWvWEGhqhvRWyqkFT1IiKTSkDfrndxuF--9g9WkAgPOlR56gIMfpQarwY0kQE7fy1K9gEcw9ln9VxxHtibSTtkbuOpLXX3LZTuzzKH3iMvjYf7-DGPpACsHG81D1dHRHU/http%3A%2F%2Fpac-md.com>

SUPPLEMENTAL MOTION FOR A NEW TRIAL

UNDER FEDERAL RULE OF CRIMINAL PROCEDURE 33

EXHIBIT B

Gmail

Sanjeev kumar <sanje45@gmail.com>

Support at FDA/DICE Re:510 k document vs ifu - 0326-00817203

1 message

"DICE" <dice@fda.hhs.gov> <dice@fda.hhs.gov> Wed, Apr 1, 2026 at 9:22 AM
To: "sanje45@gmail.com" <sanje45@gmail.com>

U.S. FOOD & DRUG ADMINISTRATION

Dear Dr. Kumar,

Thank you for contacting the Division of Industry and Consumer Education (DICE) at FDA's Center for Devices and Radiological Health (CDRH) DICE@fda.hhs.gov e-mail account.

Please join us at the Regulatory Education for Industry (REdI) Annual 2026 Conference Tuesday May 19th and Wednesday May 20th. The REdI Conference is provided at no cost and features both an in -person and online version. This year's theme is "Innovative Regulatory Strategies to Advance Medical Products", and will start with a plenary with three Center Deputy Directors followed by separate session tracks on drugs, devices and biologics. To find more information about Redi, including information on how to register, please visit https://www.fda.gov/news-events/regulatory-education-industry-redi-annual-conference-2026-innovative-regulatory-strategies-advance?utm_medium=email&utm_source=govdelivery

In response to your inquiry, regarding the 510K document for a cleared medical device versus the IFU, the FDA has regulatory authority of the medical devices themselves; to assure they are safe and effective for use, and the manufacturers conduct as it relates to the marketing and sale of their devices. The FDA has no regulatory authority over the practice of medicine (conduct of physicians and facilities like hospitals). State and

local medical boards regulate physician conduct and facilities.

Additionally, the IFU is the manufacturer's official, FDA-cleared labeling that tells you the indications for use, how to properly operate the device, warnings, precautions, and contraindications. It is specifically written for end users like physicians. A 510(k) is a regulatory submission to the U.S. Food and Drug Administration showing that a device is substantially equivalent to another legally marketed device. It may include technical data, performance testing, and proposed labeling (including a version of the IFU), however, it is not intended as a clinical instruction manual for physicians. The IFU is the controlling document for use. The 510(k) is background regulatory documentation. Please review, Device Labeling | FDA, How to Determine if Your Product is a Medical Device | FDA

I hope this information is helpful and wish you all the best. Please always consult your Primary Care Physician or Healthcare Provider regarding medical device use. If you have any additional questions, please feel free to email DICE again at DICE@fda.hhs.gov.

Sincerely,
Consumer Education Team
Division of Industry and Consumer Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Department of Health and Human Services

Original Message
From: sanje45@gmail.com
Sent: 3/31/2026

Subject: 510 k document vs ifu
Message:

Hi fda staff

A physician as the end user of a device- am i supposed to follow the 510 k document or the IFU for a surgical device during the use of a device on a patient.

IFU means instructions for use document insert with a device

Pls let me know

Sincerely
Sanjeev Kumar MD
Sent from my iPhone